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THE CAROLINA

JOURNAL OF PHARMACY

JANUARY 1992 VOLUME 72 NUMBER 1

Tom Thutt, 1991 recipient of the NARD/Syntex Preceptor of the Year Award. Story on page 21.

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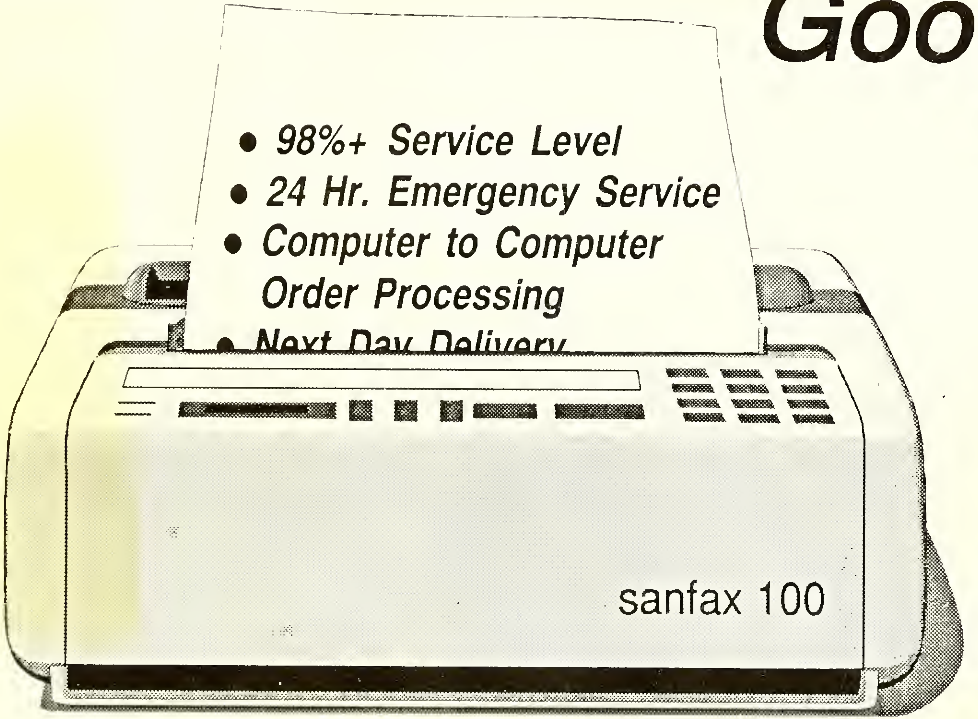

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Important figures in diabetes care

7

Diabetes is the **No. 7** cause of death in the US[1]

1

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1. *Diabetes Surveillance, 1980-1987* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation, 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

CANDIDATES FOR NCPHA OFFICE-1992

INTRODUCING THE CANDIDATES FOR OFFICE OF PRESIDENT ELECT AND MEMBER-AT-LARGE OF THE EXECUTIVE COMMITTEE

The six candidates for NCPhA office subject to the February mail election are listed below, with a brief biographical sketch of each and a statement about the number one issue facing North Carolina pharmacy in 1992–1993. You will want to keep this issue of **The Journal** to refer to when the mail ballots arrive.

This is the second year of elections under the Constitution and Bylaws adopted at the 1990 Annual Convention. There are two candidates for President-Elect and four candidates for two seats on the Executive Committee for a three-year term of office. Mr. Bizzell and Mr. Dedrick were elected last year to one–year terms on the Executive Committee, so they will rotate off. Since one of them will be elected President–Elect, the desired continuity will continue on the Committee.

The mail ballots will be mailed to NCPhA members in early February, as soon as this journal is mailed, and must be returned to the NCPhA office within thirty days of receipt. The Elections Committee will meet in early March, open and tally the ballots, with the official notice appearing in the April issue of this publication.

Successful candidates will be installed in office at the Officers Recognition and Installation Breakfast on Sunday morning, May 24th, at the Annual Convention in Pinehurst.

President Elect

W. Robert Bizzell, Kinston
Stephen C. Dedrick, Durham

Member of the Executive Committee
(two to be elected)

Pamela U. Joyner, Morrisville
John R. Setzer, Winston Salem
Rebecca A. Wheeler, Charlotte
Jonathan A. Hill, Charlotte.

W. Robert "Rob" Bizzell
Realo Discount Drug
300 N. Queen Street
Kinston

Rob Bizzell is the owner of Realo Discount Drug Store in Kinston and is a consultant pharmacist for the Lenoir County Health Department and Lenoir County Jail Clinic.

Bizzell has been a member of NCPhA since his 1976 graduation from the UNC School of Pharmacy. He is past second vice president and third vice president of NCPhA, and a current Executive Committee member-at-large. He has served as chairman of the Legislative and Resolutions Committees and he is a member of the NC Academy of Pharmacy and the Academy of Consulting Pharmacists. He is also a member of NARD. He is the 1982 recipient of the Don Blanton award, and is a Fellow of the American College of Apothecaries and a NABPLEX item writer.

Bizzell has recently been named Assistant Treasurer of the Arendell Parrott Academy, and received the 1991 Lenoir County J.C. Distinguished Service Award. He was also named one of 5 Outstanding Young North Carolinians for 1991.

Locally, Bizzell is a past president of the Lenoir-Greene-Jones Pharmaceutical Society and past vice president of the Wayne County Pharmaceutical Society. He was the 1981 Lenoir County Pharmacist of the Year.

Position Statement

While trying to decide, in my opinion, what would be the number one issue facing pharmacy in North Carolina in 1992-93, so many possibilities entered my mind. We are a changing profession with new challenges facing us almost on a daily basis. But one issue stood out above all the rest. That is the spiraling cost of Health Care, and how pharmaceuticals are a factor in this.

Whether we practice in a retail or an institutional setting, we must confront this dilemma. At the current rate of increase of drug prices, only those with some form of governmental assistance or insurance can afford medication. But with the increasing cost of medical care, insurance premiums will rise to an unaffordable level and governmental programs will be re-evaluated. Reimbursement for medication will therefore be affected, which will have a direct effect on pharmacists' worth and could limit their ability to practice pharmacy as they wish.

We must confront this situation on two levels. First, we must show the public what proper pharmaceutical care is and that it is a smart way to spend their health care dollar. We must let them know that we are not charging an exorbitant amount for their medicines, and that most of the high price lies with the manufacturer. Secondly, we must call for pricing restraint on the part of the manufacturers. If we continue to have the type of price increases we have been having, medical care will become unaffordable and a national health care plan will be next.

The future of pharmacy is bright as long as we control our own destiny. These spiraling costs can take the control out of our hands, allowing another individual or agency to dictate how to practice our profession.

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Stephen C. "Steve" Dedrick
Duke University Medical Center
P.O. Box 3089
Durham

Steve is the Associate Director of Pharmacy at Duke University Medical Center where he has practiced since graduating from UNC-CH School of Pharmacy in 1972. He completed the Master of Science in Pharmacy degree program from UNC in 1989.

Steve has been active in organized pharmacy activities for NC Pharmaceutical Association and NC Society of Hospital Pharmacists. He has been Chairman of NCPhA's Continuing Education Committee and has served on the Association's Nominating, Public & Professional Relations, and State Legislation Committees. Steve was President of NCSHP in 1985–86. He has also served as the Society's Executive Secretary. He received the 1988 Hospital Pharmacist of the Year Award for NCSHP.

In addition to memberships in NCPhA and NCSHP, Steve is a member of the American Society of Hospital Pharmacists, and the Durham-Orange Pharmaceutical Association. Steve is a member of the Kappa Psi Graduate Chapter and serves on the Board of Directors of Kappa Psi Fraternity.

Steve lives in Durham with his wife, LaRue, who is also a pharmacist. They have two children, Austin and Stephanie.

Position Statement

Economic frustration, high consumer expectations, the uninsured, and technology are focusing unprecedented attention on health care. The pharmacy profession is caught in the larger consumer concern for affordable health care that from the consumer's perspective, has no relief in sight. The next several years are important for pharmacists to continue improving their contribution to the health care system as providers of information to consumers and other health care practitioners, since alternative product distribution systems competing for pharmacy dollars abound.

The pharmacist's advantage over dispensing physicians, mail order pharmacies, or automated dispensing machines is a knowledge base of drug therapy management combined with "high-touch" accessibility. This advantage enables the pharmacist to listen to the consumer's concerns and assess their physical or mental limitations to provide consumers appropriate explanations of their medications. This process improves compliance and compliance improves pharmacy's business. Information provided to consumers by pharmacists reduces the opportunity for drug misadventures through improved consumer understanding of drug effects, side effects, and adverse reaction potential.

As the public becomes increasingly aware of the value of pharmacists by observing pharmacists actually performing these services, the forces attempting to remove or distance the pharmacist from the drug delivery/drug information system will be slowed. The public seeks full value from a health care system they do not completely understand.

It is our job to educate the public about the pharmacy services they should expect, while explaining that pharmacists are remunerated for their services, not for products. NCPhA is the state organization we can use to help us professionally, economically, and politically in the growth of Pharmacy's role in the health care system.

Rebecca Anne Wheeler
Charlotte Pediatric Clinic
1700 Abbey Place
Charlotte

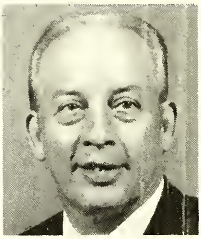
Rebecca Wheeler is Manager of Charlotte Pediatric Pharmacy in Charlotte and has been a NCPhA member for seven years. She is a past chairman for two consecutive years of the Talk About Prescriptions Month Committee. She has also served on NCPhA's Public and Professional Relations and Employer-Employee Relations Committees. Wheeler was selected by NCPhA as the 1991 North Carolina Young Pharmacist of the Year.

Wheeler is a member of the Mecklenburg Pharmaceutical Association. She is a past president of the Wake County Pharmaceutical Association and former Wake County Pharmacist of the Year. She is a UNC Practitioner-Instructor.

Nationally, Wheeler has been a member of APhA for seven years. She is a 1991 graduate of APhA's William S. Apple Program in Community Pharmacy Management. She has served in the APhA House of Delegates. Wheeler currently serves on the Glaxo Pharmacy Advisory Board and the Speakers Bureau for Smith Kline Beecham.

Position Statement

We are experiencing perhaps the most dynamic phase in the history of our profession. The opportunity for truly making a positive difference has possibly never been greater. The number one issue for North Carolina pharmacists, as well as our colleagues nationwide, is the acceptance and/or reaffirmation of a personal responsibility to affect positive professional growth. This requires individual dedication to assuming proactive rather than reactive roles with our patients, within our communities, and with other health care providers and payors. Embracing the concept of pharmaceutical care—the mission statement of pharmacy, is a responsibility of each and every one of us. We must share in this charge equally, and cause the coming year to mark renewed pride, respect, and strength in the pharmacy profession.



Jonathan A. "Don" Hill
Peak Drug Inc.
2044 N. Graham Street
Charlotte

J.A. "Don" Hill is the co-owner of Peak Health Care, Inc., in Charlotte. Prior to becoming an independent pharmacy owner in 1979, Don was President of Dixx Drugs in Florida, N.Y. and was District Manager for Eckerd Drugs in Charlotte. Don received his B.S. in Pharmacy from UNC-CH School of Pharmacy in 1955, a Bachelor of Divinity degree in 1962 and a Master of Theology degree in 1967 from Southeastern Baptist Theological Seminary.

He is a member of APhA, Mecklenberg County Pharmaceutical Association, and NARD. He has served on the NARD Computer Committee and has represented NARD as a speaker. He serves on the Executive Board of Directors for the Pharmacy Network of North Carolina. In addition, he sits on the Executive Board of Directors for Arthritis Patient Services of Mecklenberg County. Don is a Sunday school teacher for Carmel Baptist Church.

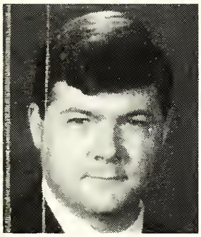
Don lives in Charlotte with his wife, Bestelle. They have three children, and three (and a half!) grandchildren.

Position Statement

I would appreciate the opportunity to work with the state association's other officers to represent all the varied interests of the state's pharmacists so that we will better our position with politicians, third party processors, reimbursement programs, federal programs and the general public.

I would come to the position with extensive chain store experience and as an independent corner drug store owner for the past twelve years. I have been an active participant in NARD and a contributing board member of one of the best pharmacy networks in the nation. With this experience and background, I feel qualified to help lead the association in voicing positive positions on political, ethical, professional, and business issues facing our profession.

The association should be aggressive in creatively contributing to and implementing ideas, technologies and methodologies for our pharmacists who are faced with a tremendously changing business and professional environment. I pledge my energies and time to these goals if I am elected.



John A. Setzer
Revco Discount Drug Center
588 Hanes Mall Boulevard
Winston Salem

John R. Setzer is a pharmacist for Revco Drug Stores in Winston-Salem. He is currently serving as a preceptor for both UNC and Campbell pharmacy students.

He has been a NCPhA member for nine years. John currently serves as chairman of the NCPhA Convention Planning Committee. He has served on several NCPhA committees in the past, and was Convention Chairman for 1991. John is a founding member of the Northwest Pharmacists Association and has served in various offices including President. He is a member of the Northwest AHEC Advisory Committee and an active member of APhA, having served as a delegate to a national convention.

Position Statement

During the next year, we as pharmacists will be forced to take a new look at patient counseling. The federal government and state boards will begin mandating patient counseling. This should not be an issue as we all should be already counseling our patients to give them the benefit of our knowledge. It is our job to help others understand how to take their medications and what they can expect from them. We took the time to learn about medications and their use, whereas others have not had that privilege. But our knowledge is of no use if we decide not to use or share it. Therefore, instead of government mandates on patient counseling, we should all make a personal commitment to educate our patients about their medication.

Pamela U. "Pam" Joyner
Wake Area Health Education Center
P.O. Box 14465
Raleigh, NC

Pam Joyner is the Director of Pharmacy Education for the Wake County AHEC and has been a NCPhA member for 16 years. She has participated on a number of NCPhA committees - Executive Committee, Continuing Education, Nominations, Social and Economic Relations, and Public and Professional Relations. She is a member of the Academy of Pharmacy.

Pam is a member and past president of NC-SHP and a member of APhA, ASHP, and AACP. She is past recipient of the NCSHP Continuing Excellence Recognition Award. She is also a past president of the Wake County Pharmaceutical Association. She is currently serving as President of the Pharmacy Foundation of N.C.

Position Statement

The newly adopted mission statement for pharmacy in North Carolina gives pharmacists the opportunity to unite and support a common philosophy of practice where we focus our activities on helping patients achieve the therapeutic outcomes expected from their therapy. As we begin 1992, we need to focus our knowledge and expertise on helping people make the best use of their medications. In this era of high technology and a rapidly changing system of health care delivery, we need to work together as a profession to accept new and increased responsibilities for patient care.

NCPhA represents pharmacists who impact patient care in a variety of health care settings. I believe that it is important for NCPhA to help its members maximize their opportunities. Our Association needs to provide the leadership, education, resources, and insight that will help its members prepare for and anticipate their future pharmacy practice.

I would be honored to serve as your representative and ask for your support in meeting the challenges which face our profession and NCPhA.

WELCOME!!! NEW NCPHA MEMBERS WHO HAVE JOINED SINCE OUR LAST LISTING

Bridgit M. Walker, *Roxboro*
Karen A. Bencuya, *Thomasville*
Ben F. Cooper Jr., *Fayetteville*
Javotte L. Driggers, *Asheville*
Kimberly B. Hoffman, *Gastonia*
Delvin S. Huffstetler, *Emerald Isle*
Herb Patterson, *Chapel Hill*
Wesley S. Schley, *Cary*
David W. Smith, *Raleigh*
Martha C. Smith, *Raleigh*
David John Tauber, *Chapel Hill*
Mark P. Tompkins, *Greensboro*
Gene Woodall, *Raleigh*
A.P. Alexander Jr., *Morehead City*
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Larry Blank, *Greensboro*
Ross Brickley, *Raleigh*
Virginia L. Burton, *Raleigh*
Bruce Carlton, *Clinton*
Gary D. Cornwell, *Lincolnton*
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Carol A. Gatlin, *Chapel Hill*
Ed Hesterlee, *Kansas City MO*
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Lisabeth J. Saunders, *Eden*
Van D. Weaver, *Raleigh*

THE NEW JOB FROM DAY ONE

This is the twenty-first in a series of articles for professionals who manage and managers who lead professionals, and those who are both. Pharmacists operate with one license, but fill many different roles in hospitals, chain stores, individually-owned stores, industry, and educational settings. Along the way, they need a variety of management skills. These articles take a broad perspective on management concepts we hope you will be comfortable applying.

For even the experienced manager, there is much uncertainty in taking over a new position. Even if you know the business, you do not know the people nor they you. You may not have worked for your immediate boss before. The people reporting to you will be new and you will have to find out where and how much you can rely on them. Worst of all, you believe that you only have a few weeks, or days, or hours, or minutes to gain control of the situation. Whether or not it is true, you feel like those first actions can make or break you.

John Gabarro in *The Dynamics of Taking Charge* suggests that there are five stages to what he defines as "not...just orienting oneself to a new assignment,...(but) the process by which a manager establishes mastery and influence in a new assignment."[1] An earlier article in this series focused on the joining-up process, the development of the psychological contract that one needs to start a job.[2] But that contract is between you and your superiors, it offers much less guidance in problem-solving and managing downward once one is in the new job. Gabarro's five steps are:

Taking Hold—initial orientation, problem solving and fire-fighting.

Immersion—really learning the job and the business in depth.

Reshaping—making one's own mark on the organization based on the findings of the immersion stage.

Consolidation—Assessing the actions of the reshaping moves and tying up the loose ends.

Dr. Curtis P. McLaughlin

Refinement–fine tuning and scanning the environment for further change needs.

These five stages are not defined as much by time periods as they are by the primary activities taking place in them. All involve learning and action, but with differing emphases during each stage. The work content for the manager at each stage focuses on getting the right processes in place, building up relationships and trust with people, and gaining implementer involvement and support. All of these stages and how best to cope with them are highly dependent on the circumstances one finds upon arrival.

Taking Hold

Taking hold begins with a knowledge of why you are being put in the job and the fate of your predecessor. That is something to check out during the joining up process. Was my predecessor promoted for good performance or transferred (fired) for poor performance?

CURTIS P. MCLAUGHLIN is a Professor of Business Administration in the School of Business and Professor of Health Policy and Administration in the School of Public Health at the University of North Carolina at Chapel Hill. This article has been made possible through an educational grant from **Marion Merrell Dow, Inc.,** *Kansas City, MO.*

continued on page 13

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What do you expect from me? How does that compare to the current level of performance? Are there obvious or covert practices that top management thinks need changing? Is this a turnaround situation? If there is such an issue, it will get your top attention, but your primary task is to get some breathing space until you have a chance to immerse yourself in what is going on and come up with your own ideas as to how things ought to be done. The luckiest of managers is one who walks in and during this period of orientation and evaluation sees something that from past experience he or she knows should be changed, something which immediately improves the bottom line results. Having made an initial score, the manager can get down to the foot-slogging work of finding out what needs to happen over time.

Immersion

This period involves really getting to know the people and the potentials of the situation for meaningful change. It involves figuring out what would work in the future and looking at the unintended consequences of any changes made while taking hold. Many managers get into trouble for not acting fast enough, but a significant number also get into trouble by acting too fast, by taking actions that senior management perceives as ill-considered. This is also the time to get the implementers involved, to ask them to look at situations and make their own recommendations for dealing with perceived problems.

Reshaping

With the fire–fighting of the Taking Hold period over and the deeper knowledge of the Immersion period internalized, the new manager makes the organizational and personnel changes that should lead to the desired performance outcomes. This is a period of intense activity, selling the new solutions and working out the details of implementation. It is the activity that most people think about when taking hold is discussed.

Consolidation

After the hectic activities of the reshaping period things settle down to a calmer pace as people observe and monitor the results. As problems surface with the new regimen, they are fixed as soon as people and resources become available.

Refinement

At some point the manager is no longer new, but the initial program still must be fine-tuned. At the same time the environment is changing, and the now "old" manager must begin to look forward toward new responses to new situations.

Timing

The timing of these phases depends on how much experience the new manager has with this firm and on the expectations of higher management. Insiders will usually take less time in the Immersion phase and move more rapidly toward reshaping the organization. If management is expecting the new person to turn around a poorly performing unit, there is little opportunity to spend much time in the Immersion stage. The experienced manager will probably already have relationships with key actors inside the firm and out. A frequent problem at this stage is clashes of management styles between new managers and their supervisors. Gabarro suggests that "a manager's prior experience and skill base make a difference and are not to be ignored in succession planning" and "the all-purpose manager who can be slotted into just about any organization, function, or industry exists only in management textbooks." (pg. 68)

The key to success in taking hold seems to be the ability to enlist the assistance of those already there, especially through "problem-focused task forces." Failure seems to be associated with the "Lone Ranger" syndrome. (pg. 77) The payoff from enlisting others comes through developing shared expectations with the implementers, from building mutual trust, in building a working team, in facing rather than avoiding conflict, and in assessing the ability of the individuals who are there to contribute to the change process.

Building trust cannot be rushed, neither can building a team. If the right people are not there, they have to be found and recruited. So, while the taking-hold process does not give the manager a lot of time, the manager must buy time to develop a team, while still exhibiting requisite leadership and sense of competitive urgency. That is not an easy balancing act, but it is an important one to every manager who is new on the block. Think through how you are going to take hold when accepting a new supervisory position.

1. John J. Gabarro, The Dynamics of Taking Charge, Boston, MA: Harvard Business School Press, 1987, p. 6.

2. C.P. McLaughlin, "The Joining-Up Process," The Carolina J. of Pharmacy, 69:4, April 1989, pp. 11,12,25.

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GEORGIA LEWIS ELECTED TO WONARD OFFICE

Georgia L. Lewis, a Charlotte attorney, was elected 4th Vice President of WONARD, the Women's Organization of the NARD in November. She and her husband, Robert L. Lewis, represented Avondale Pharmacy at the national NARD conference in Baltimore, Maryland. The Lewis's were happy to renew acquaintances with "On the Road" correspondent, Charles Kuralt, who was one of the keynote speakers at the November conference.

Robert is a pharmacy school graduate from UNC-Chapel Hill and is President of Avondale Pharmacy in Charlotte. Their daughter, Sonya Lewis, is also a UNC pharmacy graduate and is teaching this year at the School of Pharmacy.

Georgia L. Lewis

Georgia also serves on the Alternative Dispute Resolution Committees for the American Bar Association's YLD Division, the Mecklenburg County Bar, the Charlotte-Mecklenburg Community Relations Committee and serves as Vice Chair of the NCBA'S YLD Special Project's Committee on the Homeless. Georgia is in the unique position of simultaneously belonging to both the Senior Division and the Young Lawyer Division of the North Carolina Bar Association. She is in private practice in the areas of Wills and Estates, Social Security Disabilities and Guardianships.

One of Georgia's duties on the WONARD board is that of Legislative Chair. She is encouraging all pharmacy–related participants to contact their U.S. Senators and U.S. Congressmen and urge them to support H.R.9 and S.430. These bills are known as the "Insurance Competitive Pricing Act." Pharmacists' support of this legislation is crucial to pharmacy (and consumers in general.) H.R. 9 could be voted on in February. •

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Telephone: 919-942-4454

PERMITS ISSUED

9/16/91
Kmart Pharmacy
606 W. 15th Street
Washington
Susan Meier Eggers
Pharmacist-Manager

Todd's Northside Professional Pharmacy
1141 North Road Street
Elizabeth City
Martha Bennett Paylor
Pharmacist-Manager

The Tabor City Medicine Mart, Inc.
130 S. Main Street
Tabor City
Jaclyn Caroline Cox
Pharmacist-Manager

Kmart Pharmacy
150 Becker Village Mall
Roanoke Rapids
James Floyd Barden III
Pharmacist-Manager

Greensboro Pharmacy
441-B Battleground Avenue
Greensboro
William Randolph Mize Jr.
Pharmacist-Manager

9/19/91
Revco Discount Drug Center
13 Highway 17 South
Hampstead
Dana Langdon McClure
Pharmacist-Manager

10/01/91
Lowell Drugs
105 E. First Street
Lowell
Harold Clifton Hearne Jr.
Pharmacist-Manager

10/7/91
Eckerd Drugs
4215 Providence Road
Charlotte
Trudie Durden Grigg
Pharmacist-Manager

Pyramid Drugs
1056 National Highway
Thomasville
Clyde Dean Bryson
Pharmacist-Manager

Eckerd Drugs
Route 1, Box 1028-A
Banner Elk
Ronnie Dwaine Proffitt
Pharmacist-Manager

continued on next page

10/7/91
Kmart Pharmacy
980 Brevard Road
Asheville
Daniel Lynn Barnett
Pharmacist-Manager

Wal-Mart Pharmacy
6600 Glenwood Avenue
Raleigh
Suzanne Marie Trunk
Pharmacist-Manager

10/14/91
Kerr Drugs
Winter Village Shopping Center
Winterville
Deborah Clark Hemingway
Pharmacist-Manager

10/21/91
Kmart Pharmacy
1122 Randolph Street
Thomasville
Sharon Canipe Beck
Pharmacist-Manager

10/28/91
ABCCM Medical Clinic
491 Biltmore Avenue
Asheville
Daniel Gilbert Garrett
Pharmacist-Manager

11/1/91
Gamma Rx
141 Glenn Bridge Road
Arden
George Kennedy Cawthorne
Pharmacist-Manager

11/4/91
Co-Care Industrial Pharmacy
Highway 220
Seagrove
James Wiley Cole
Pharmacist-Manager

Davidson Medical Ministries
Clinic Pharmacy
25 E. Third Street
Lexington
John Fuller Harman Jr.
Pharmacist-Manager

Owen Home Infusion
4600 Park Road, Suite 103
Charlotte
Warren Stephen Binnick
Pharmacist-Manager

11/5/91
Mast Discount Drug
933 College Street
Oxford
Julie Kent Forehand
Pharmacist-Manager

11/14/91
Clarks Drug Store
123 S. Colle Street
Warsaw
Randloph Fletcher Spainhour
Pharmacist-Manager

11/18/91
Planned Parenthood of the Capital & Coast
100 S. Boylan Avenue
Raleigh
Susan Gretz Aycock
Pharmacist-Manager

Wal-Mart Pharmacy
3000 S. Horner Boulevard
Sanford
Larry Thomas Mathis
Pharmacist-Manager

Winyah Dispensary L.T.C
of North Carolina, Inc.
118 W. Main Street
Aberdeen
James Ervan Heinz
Pharmacist-Manager

TAR HEELS INSIDE THE BELTWAY

"Tar Heels Inside the Beltway" *is a new feature, presenting articles and points of view from noted pharmacists with North Carolina affiliations who work in the Washington, D.C. area. Many are key staff or managers with national pharmacy organizations and others work in government, and will present a perspective on pharmacy issues unique to their positions. We hope you enjoy this series and invite your comments. Naturally, the opinions expressed are those of the authors and may not reflect those of the North Carolina Pharmaceutical Association.*

THE IMPACT ON PHARMACY OF NATIONAL HEALTH PROMOTION GOALS FOR THE YEAR 2000

By: Steven R. Moore, B.S. Pharm., R.Ph., M.P.H., F.R.S.H.
Captain, U. S. Public Health Service
Health Resources and Services Administration
Rockville, Maryland, U.S.A.

Summary: The United States public health sector develops national goals for health promotion through the federal government for ten year cycles. The impact and involvement of pharmacy in the process and the potential implications for pharmacy in the arena of public health are examined.

Note: The opinions expressed in this paper are purely those of the author and do not necessarily reflect the opinion or policy of the Agency or Public Health Service.

Analysis: *It appears that pharmacy has little role in the national public health agenda*

Background: The United States does not have a formalized national health service, but has a very intricate mix of federal, state and local resources (public sector), as well as multiple private practice professionals and institutions (private sector). The federal leader in health is the Department of Health and Human Services, whose secretary reports to the President. Within the varied departments, the Public Health Service provides the true health component of the department.

The Public Health Service (PHS) is composed of 8 agencies: the Alcohol, Drug Abuse and Mental Health Administration; the Agency for Health Care Policy and Research; the Agency for Toxic Substance and Disease Registry; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; the Indian Health Service; and, the National Institutes of Health. The head of the PHS is the Assistant Secretary for Health (ASH), a political appointee. Serving under the ASH is the Surgeon General, the chief federal government spokesperson on health.

In addition to such diverse roles as regulation (Food and Drug Administration), biomedical research (National Institutes of Health), specialized health care delivery (Indian Health Service), and disease surveillance (Centers for Disease Control), the PHS seeks to involve its agencies and the public in health promotion activities. The most visible example of this joint effort is the Health Objectives for the Nation, a ten year cycle of health promotion goals for the nation's health.

Although these goals have no mandated authority and usually have no direct federally funded support, they are utilized across the patchwork quilt of health care in the United States to develop strategies and interventions to promote the health of the population. State health departments utilize the benchmarks to assure that they are conforming to national norms. Local health departments use the goals to develop narrowly focused efforts, within their limited resources. Trade groups and private industry use the goals to divert practice directions into areas of greatest need. In short, these goals become the national blueprint for health.

Healthy People 2000 is the latest edition of the national goal setting. Healthy People 2000 has as its stated goals: to increase the span of healthy life for Americans; to reduce health disparities among Americans; and to achieve access to preventive services for all Americans. Released at a national conference in Washington in September, 1990, the goals are the result of a lengthy process of public input, discussion, negotiation and refinement. The 673 page document that was released at this conference was the final product of the effort.

The diverse set of goals is divided into three major groups: health promotion; health protection, and preventive services. The health promotion strategies involve individual lifestyles which in turn can impact individual health status. These goals include topic areas in physical activity and fitness, nutrition, tobacco, alcohol and other drugs, family planning, mental health, and violent and abusive behavior.

The health protection strategies involve environmental or regulatory areas that impact the general population. These goals include topic areas in unintentional injuries, occupational safety and health, environmental health, food and drug safety, and oral health.

The preventive services strategies involve impacts upon individuals through effects in various clinical settings. These goals include topic areas in maternal and infant health, heart disease and stroke, cancer, diabetes and chronic or disabling conditions, HIV infection, sexually transmitted diseases, and infectious diseases. One additional section at the end of the groups of categorical goals addresses surveillance and data systems, since one of the real problems associated with the 1990 goals was the lack of ongoing data systems, to evaluate their impact and effectiveness.

Pharmacy Impacts: A review of the outcomes indicates that the following goals have a pharmacy component, predominant impact upon pharmacy practice, or an obvious parochial interest for pharmacy.

Topic: Food and Drug Safety

Increase to at least 75 percent the proportion of pharmacies and other dispensers of prescription medications that use linked systems to provide alerts to potential adverse drug reactions among medications dispensed to different sources to individual patients. (Baseline data available in 1993.)

Increase to at least 75 percent the proportion of primary care providers who routinely review with their patients aged 65 and older all prescribed and over-the-counter medicines taken by their patients each time a new medication is prescribed. (Baseline data available in 1992.)

Topic: Heart Disease and Stroke

Increase to at least 50 percent the proportion of people with high blood pressure whose blood pressure is under control.* (Baseline: 11 percent in 1976-80, estimated 24 percent in 1982-84.)

Increase to at least 90 percent the proportion of people with high blood pressure who are taking action to help control their blood pressure.* (Baseline: 79 percent of aware hypertensive taking action in 1985.)

Topic: Clinical Preventive Services

Increase the proportion of all degrees in the health professions and allied/associated health profession fields awarded to members of under-represented racial/ethnic groups as follows: Blacks - 8% (Baseline 1985-85 - 5%); Hispanics - 6.4% (Baseline 1985-86 -3%); and, American Indians/Alaska Natives - 0.6% (Baseline 1985-86 - 0.3%).

*Pharmacy not expressly mentioned but highly implied.

Analysis: It appears that pharmacy has little role in the national public health agenda. Of the 271 members of the Healthy People 2000 Consortium (made up of voluntary, professional, trade, and public interest groups) listed in the final report, there were five pharmacy organizations. Their impact did not appear significant in the final output.

This lack of impact can possibly be attributed to a variety of factors. First, appearances in these goals do not indicate that pharmacy is a legitimate player in the public health arena. The field of public health is a great believer in those who pay their dues, get the rewards. The goals were not originated by some mystical power, but were the result of pro-active initiation by players in the area of public health, who were able to defend themselves to their peers for eventual success in inclusion. There appears to be no success for pharmacy in the area of active inclusion of objectives, nor in the text that is descriptive of each objective in the report. Pharmacy does not exist in the vast majority of this national report and the public health standard.

Second, great truisms that are promoted within the pharmacy literature do not appear to have been legitimized by this report. The pharmacist as the public health educator, the pharmacist as the vital first link in contact with patients, the pharmacist as the active participant in the local community, and the pharmacist as the active primary care provider, are all recurrent themes in the pharmacy literature. In the arena of national health promotion goals, these were non-entities.

Third, the vital component of public health that is public health policy formation appears to be removed from organized pharmacy's impact. It is often said that the extent of organized pharmacy's real interest in Washington and other loci of public health policy is purely economic. There is very little direct monetary gain to be obtained from these objectives, but the practice of the profession can be dramatically affected by their implementation. It takes a long term perspective and knowledge of the broader arena of public health to see the impact on professional practice of these objectives, but this apparently did not happen with pharmacy.

Fourth, the final product does not indicate a critical review by pharmacy. For example, the section on "Alcohol and Other Drugs" has the term "drugs" very much identified as illicit or illegal drugs. Pharmacy review allowed the mistaken perception that this negative connotation is inclusive of drugs in general. This entire section is dealing with abuse of drugs and largely with illegal drug use. The critical review and clarification of this matter before it becomes public, could do much to decrease a public perception that "drugs" are equated with bad or illegal activity.

Fifth, there is no real public health pharmacy group and the established pharmacy organizations certainly did not assume the role for the purposes of this document. There was apparently no internal PHS pharmacy input or activity either. The final results speak for themselves, in this regard.

Once again, pharmacy failed an excellent opportunity to involve itself with the integrated structure of public health. This is by no means a problem only in the United States, but this activity provides a glowing example of how passivity in the public health arena results in very minimal results for pharmacy. •

Left to Right: NARD President Bill Katz, Tom Thutt and Jenny Partridge, Manager, Healthcare Marketing Development and Pharmacy Programs, Syntex Laboratories at the presentation of the NARD/Syntex Preceptor of the Year Award. Photo by Oscar & Associates.

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TOM THUTT CHOSEN NATIONAL PRECEPTOR OF THE YEAR

Thomas R. Thutt, a preceptor in the University of North Carolina at Chapel Hill School of Pharmacy, has been chosen the NARD/Syntex Preceptor of the Year. Thutt, a Kinston pharmacist, received the honor at the NARD National Convention and Trade Exposition in Baltimore, MD, October 27-31.

The award recognizes a pharmacist who has made a significant contribution to the education of pharmacy students through his time, talent and effort as a preceptor. The NARD's National Center for Independent Retail Pharmacy presents the award with support from Syntex Laboratories.

Thutt, owner and pharmacist–manager of Medical Center Pharmacy in Kinston, received an engraved plaque as well as travel and lodging expenses to the convention. In addition, Syntex Laboratories will contribute $1,000 to the UNC-Chapel Hill School of Pharmacy in his honor.

Thutt has served the School of Pharmacy as a preceptor for 16 years and has been a practitioner-instructor in its Academic Internship Program for a decade. Preceptors oversee externships for pharmacy students in such settings as pharmacies, hospitals and industry, government or professional organizations.

Thutt has coached students preparing to take the state licensing examination, and was a member of a pharmacy school task force that revised the "Academic Internship Manual for Program Instruction."

School officials say he is an excellent role model for students. "Mr. Thutt radiates an enthusiasm about pharmacy and about health care that is not often seen. He has a genuine concern for his patients and the practice of pharmacy and sets a strong example for our fifth-year students," wrote June H. McDermott. McDermott is a clinical assistant professor and director of the school's Practitioner-Instructor Development Program, UNC School of Pharmacy and nominated Thutt for the national award. Thutt won Syntex's North Carolina Preceptor of the Year Award in 1987 and 1990.

Besides serving as a preceptor, Thutt has presented continuing education seminars on the moral, ethical and legal aspects of pharmacy for pharmacy professionals across North Carolina.

Thutt's professional service has included chairing the Down East Pharmaceutical Society's nominating committee in 1988 and the NC Pharmaceutical Association's Ethics, Grievance and Practice Committee and the Continuing Education Committee. He has been a member of the NCPhA for over 17 years and has served on the Third Party, Nominations, Time and Place, Tripartite Committees and the Pharmacy Recovery Network Task Force.

Thutt received the 1990 Merck/NARD Demonstration Project Grant in Community Pharmacy. He is also a member of NARD.

A native of Sylva, Thutt earned his pharmacy degree from UNC-Chapel Hill in 1973. He was employed at Tart & West Druggists in Roseboro, Bobbitt's College Pharmacy in Winston-Salem and Hood Pharmacy in Kinston before becoming owner-manager of Medical Center Pharmacy. He was president of the Forsyth County Pharmaceutical Society and is a member of the American Society for Pharmacy Law. •

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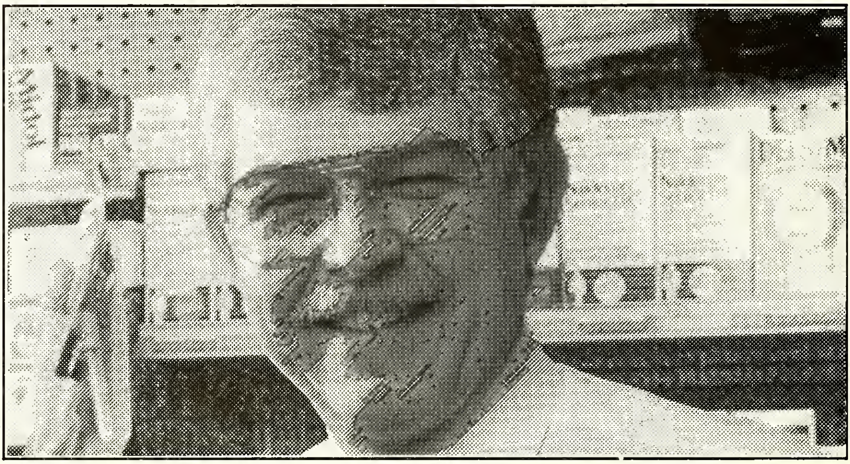

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DICKINSON'S PHARMACY

FDA'S KESSLER WARNS YOU!

Within five years, the big debate about mail-order vs. retail pharmacy will be over and the winner will be known. The brilliant young physician-lawyer who heads FDA, David A. Kessler, says he knows the winner already — the pharmacies that most ably provide what the public wants most from pharmacy: drug information.

Kessler has committed FDA's support, through upgraded package inserts and moral leadership, to spurring private-sector, voluntary supply of this information.

By coincidence, even as Kessler was announcing this, USP honored a single mail-order Rx company (Medco) for reaching three times as many patients as all independent pharmacies combined (30 million USP patient information leaflets distributed, vs. 10 million)!

Not once, he says, has he been counseled by a pharmacist about the medications dispensed.

As a father of two young children, Kessler often goes into pharmacies to get prescriptions filled. Not once, he says, has he been counseled by a pharmacist about the medications dispensed.

In the December 5 issue of the *New England Journal of Medicine*, Kessler chided both his own profession and pharmacy for not doing a better job in disseminating drug information, especially risk information (which a 1984 CBS study found is what patients want most). Physicians "need to reexamine the amount of information they give their patients and the way they deliver it," Kessler wrote. "In addition, they need to acknowledge that pharmacists should have a larger role in patient education and advise their patients to expect counseling when they fill their prescriptions."

"Pharmacists should reinforce the instructions of physicians by direct counseling. Since as many as 85% pf patients are reluctant to ask questions, the pharmacist should initiate the conversation."

Kessler also wants patients to be given a printed information sheet as well, and he endorses the very USPDI sheets that Medco's National Pharmacies were rewarded for disseminating. Ideally, he told this columnist, USPDI — or other —information could be printed out for each patient on the pharmacy computer from already marketed software (to order from USP, call 1-800-227-USPC).

Retail pharmacies have an advantage here. Former Medco employees have testified repeatedly as to how USP's leaflets are abandoned in the high-speed rush to get those Rx packages out the mail room door. While Medco may well have purchased 30 million leaflets from USP, such testimony suggests that fewer have actually gone out to Medco Rx recipients (we hesitate to call them "beneficiaries").

Individual, one-at-a-time printouts—perhaps customized to bear the patient's own name at the top —dispensed with the physical medicine and the pharmacist's oral words of advice represent the ideal solution to the patient information problem, in Kessler's view. "People want information, they deserve information," he told us. "And we have got to give them information in the right kind of format. Advertising is not the right kind of format… I think the pharmacy community recognizes that it needs to do a better job and wants to do a better job."

Under his direction, the FDA is developing a new-look package insert for new drugs that are approved, to incorporate a lay-language patient information section. Unlike the 1980 uproar over FDA-written PPIs, it won't be mandatory for pharmacists to dispense these new inserts.

"We already have it," Kessler said. "If you look at the package insert for Prozac, it has a section buried in paragraph 55, 'Information for Patients.' Well perhaps we need to have a separate stand-alone section that the pharmacist can use as a prestanding format."

That would accomodate only new drugs, as part of the FDA approval process. Established drugs could be handled by FDA on a class basis, or left with private sector marketers, such as USP. FDA hasn't made up its mind about that.

Kessler senses "considerable interest" in patient information among manufacturers, who see better patient compliance yielding both product liability benefits for themselves as well as increased sales.

In his jawboning with pharmacy interests, Kessler has been blunt. He has told them, he says, that "unless the pharmacy community does this, my sense is the world will pass them by. What is the prime issue today? You have a profession that is to some extent in search for its own identity. And my sense is that this is where the future of the profession needs to focus, because the alternative is the European system of unit packaging with patient information incorporated by the manufacturer. Again, what we are talking about is counseling, we are not talking about just information sheets."

This young, vital FDA commissioner has taken just 12 months in Washington to capture both the attention and the mindful respect of the health establishment. Without showing any partisanship, he is displaying a fervent advocacy of one-on-one, traditional pharmacy. His comments give the profession five years to answer the challenge facing it. But he cannot know for sure if that's what the marketplace will really allow. Pharmacy should not dally.

"With the price of a PC being what it is and a printer being what it is, I think it is good business," Kessler said. "Certainly it is good business for the pharmaceutical firms. It's compliance, the more people know about their drugs, the greater the likelihood they're willing to take their medicines and be in compliance. That translates into sales for everybody." ●

Dickinson's Pharmacy is presented on a grant from "Dickinson's Pharmacy – The Independent Voice," a professionally stimulating monthly newsletter available for $45.00 annually. Send a check and your pharmacy's label to Ferdic Inc., P.O. Box 848, Morganton, WV 26507–0848

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JOINT COMMISSION OF PHARMACY PRACTITIONERS FALL MEETING REPORT

Food and Drug Administration Commissioner David Kessler and Associate Director for Pharmacy Affairs Thomas McGinnis met with the Joint Commission of Pharmacy Practitioners at the Commission's quarterly meeting in Arlington, VA to discuss items of mutual interest. Members of the Commission provided recommendations to them on compounding of prescription products, essential elements of patient counseling and patient information, distribution systems for pharmaceutical products, reporting systems for adverse drug reactions and problems with prescription medicines and the selection process for F.D.A. Advisory Councils. Dr. Kessler expressed interest in a number of these issues and a firm commitment to work with the J.C.P.P. in future activities of the F.D.A.

The Commission received reports from member organizations and J.C.P.P. subcommittees on the following issues: Meeting with P.M.A. Officials, Distribution Systems for Pharmaceutical Products, One Symbol for Pharmacy, NABP Model Pharmacy Practice Act, Pharmacy in the 21st Century III Conference, Postgraduate Education & Training, Proposed Mission Statement, National Health Insurance, American Red Cross Proposed Statement, Pharmaceutical Care, Uniform Expiration Dating, and Postgraduate Educational Programming.

Members of the Commission will continue to meet with F.D.A. officials and representatives from the pharmaceutical industry. The Commission will continue to provide comments and suggestions on the draft NABP Model Pharmacy Practice Act. •

Members of the J.C.P.P. with FDA Commissioner Kessler (fifth from right, second row) include representatives from the American Association of Colleges of Pharmacy, American College of Apothecaries, American Pharmaceutical Association, NARD, American College of Clinical Pharmacy, National Association of Chain Drug Stores, National Association of Boards of Pharmacy, American Society of Consultant Pharmacists, American Society of Hospital Pharmacists and the National Council of State Pharmacy Association Executives. Photo by Bruce Reedy.

PHARMACY LAW CAPSULE

by James A. Boyd, Pharm.D., M.B.A.
Assistant Professor
Department of Pharmacy Practice
Campbell School of Pharmacy

James A. Boyd

DOCUMENTING PATIENT REQUESTS FOR DISPENSING PRESCRIPTIONS IN NON–CHILD PROOF CONTAINERS.

Consumer Product Safety Commission Regulation pertaining to the Poison Prevention Packaging Act of 1970 (16 Code of Federal Regulations SS 1700-1704) set forth guidelines for closures on prescription and non-prescription drugs, chemicals and hazardous substances. The law mandates pharmacists to dispense oral prescription and OTC products in Child Safety vials and bottles unless:

1. The patient specifically requests the non-child proof container.

2. If the pharmacist resells an OTC product packaged in a non-child safety container by the manufacturer which was approved. The Act allows the manufacturer to sell one size of an OTC product in "exempt" packaging. This provision was included for the elderly and handicapped.

3. If the prescription product is "exempt," for example, sublingual nitroglycerin.

When patients request non-child proof containers, it is in the pharmacist's best interest to record the request on the back of the prescription and have the patient sign the request. This act permits the pharmacist to honor a patient's blanket request to dispense all prescriptions in non-child proof safety containers. Again, it is advisable the pharmacist receive this request in writing. The act forbids the pharmacist to honor a blanket request by the physician, but the physician may request non-child proof containers on individual prescriptions. This section facilitates physicians telephoning prescriptions to the pharmacy.

In a recent study by Ken Baker ("A Study of the Causes of Malpractice Claims," Pharmacy Law Annual 1991, in press), one hundred consecutive claims of a major pharmacy insurance company who provides professional liability insurance for pharmacists were examined. Two percent of the claims filed against pharmacists for negligence involved the omission of safety closures on prescriptions. According to Mr. Baker, two claims per 100 filed is a very high and significant number, particularly when pharmacists are at risk of voiding his or her professional liability coverage. As discussed in the November 1991 issue of Pharmacy Law Capsule, a violation of a statute or law may invalidate the professional liability insurance coverage. Most policies clearly indicate when an action violates a law or statute the insurance coverage is null and void. •

ACROSS THE STATE

This column features news briefs about people, places and events related to pharmacy in North Carolina, and also about North Carolina pharmacists and other friends of pharmacy who must be out of the Tar Heel State for one reason or another. The NCPhA staff and The Journal's Editorial Advisory Board welcome and solicit your contributions to this column. Photos (black and white, preferably) are also welcome.

Send us your news!

Bill Medlin, UNC-1962, is recovering from a heart transplant in Norfolk and would like to hear from his colleagues and classmates. Bill's address is 4240 Thistle Drive, Portsmouth, Virginia 23703.

The *Wombles* of Plymouth, NC are featured in the January 1992 issue of *The State* magazine. The article by Shirleyan Beacham Phelps, titled "Long Live the Soda Fountain," relates the 50+ year history of Womble Drug Store with pictures of the store and the Womble family of Doc, Edith, Logan, Ed and Nyal.

Births

Michael and *Beverly Helton Best* announce the birth of Tyler Michael Best on January 10, 1992. Beverly is a 1987 graduate and Mike is a 1986 graduate of UNC School of Pharmacy.

Edwin and Laurie Link, Wilmington, announce the birth of their second daughter Mary Margaret, on November 27, 1991. Mary Margaret weighed in at 7 pounds 4 ounces and was 19 1/2 inches long. Pharmacist Link can be found at the Medicine Shoppe on Market Street.

Marriages

Lauren Lois Bunting (UNC-1988) and Timothy John Burick, both of Asheboro, were married December 28, 1991 at the First United Methodist Church in Asheboro. Lauren is employed at Prevo Drug in Asheboro.

Congratulations to *Dennis Williams* who was selected the Outstanding Academy of Students of Pharmacy Advisor by the American Pharmaceutical Association. Dennis will receive his award at the APhA Annual Meeting in San Diego in March. Dennis is the faculty advisor at UNC School of Pharmacy. *More next month.*

Robberies, Burglaries and other Illegal Activities

Raleigh: A pharmacist at a Revco store foiled a robbery attempt when he refused to give a robber the drugs that were demanded. The would-be robber with a stocking over his face held his hand in his coat pocket as if he had a gun and requested several controlled substances. When the pharmacist said no, the robber left the store and fled.

Mocksville: A burglary was interrupted by a county sheriff's officer on Thursday night, December 5, 1991. On regular patrol about 2:00 am, the officer heard an alarm sound in the Crown Drug in Hillsdale and spotted a man leaving the store. The officer gave chase and found the car in a field with stolen cigarettes still in the car. The suspect ran into the woods.

King: Three Forsyth County women were arrested and charged with attempting to get forged prescriptions filled in early December. The prescriptions were written on Reynolds Health Care Center forms and were presented at the King Drug Store. The women were successful at another King pharmacy in having a forged prescription dispensed. They were charged with violation of the Controlled Substances Act.

continued on next page

Morganton: The Revco Store on East Fleming Drive was broken into on Sunday, December 13, 1991. Prescription drugs were listed as being stolen.

Sybil Austin Skakle, Chapel Hill pharmacist and NCPhA member, is featured in the December 1991 issue of *The State* magazine. Skakle wrote the article "The Legacy of Billy Mitchell" which appears on page 14 of this issue. She is the subject of "One Last Word" which is the final feature in the magazine on page 46.

Lynn McCaskill, Ellerbe pharmacist and Richmond County Commissioner, resigned from the Low-Level Radioactive Waste Management Authority that is charged with selecting a landfill site. McCaskill is suing the Authority to keep the landfill out of Richmond County.

Hal Reaves presented a talk "Are You Taking Your Medicine Correctly" at the Pinehurst Rehabilitation Center, December 10, 1991.

Dees Drug Store, Burgaw, owned by *Frank Purdy*, celebrated its 75th anniversary in December.

Tommy Dagenhart Jr., pharmacist-manager of Nalle Clinic Pharmacy in Charlotte, was named a recipient of the **MSD Pharmacist Achievement Award**. The award is given to recognize civic and professional achievements of pharmacists.

Richard Becker of New Bern has joined the staff of the ValuRx Pharmacy in Aurora. A native of New York, Becker moved to the North Carolina coast about four years ago to escape the pace of the big city. *Aurora ought to do that.*

Gene Newsome, a partner with Family Pharmacy in Newport, has been elected President of the Crystal Coast Pharmaceutical Association.

W. B. "Bill" Halsey was honored by Alleghany Memorial Hospital on November 25, 1991, when he was named trustee emeritus in recognition of 24 years of service to the hospital. Halsey came to Sparta in 1949 and opened Halsey Drug Store. When the hospital opened, Halsey donated his time as pharmacist until the hospital employed a full-time pharmacist.

Jack L. Alexander, Highlands, has sold his store, Highlands Pharmacy, to Sherry and David Sims. Jack operated the store for the past 20 plus years.

W. Whitaker Moose, Mount Pleasant, has been elected to the NARD Executive Committee. Last year Whit served as Secretary-Treasurer.

Obituaries

Sara Fountain Lore, Winston-Salem, died December 19, 1991 at Forsyth Memorial Hospital after a year of declining health. A 1956 graduate of the UNC School of Pharmacy, Lore was the owner of Flynn's Drug Store. She was 58 years old.

William R. Adams Jr., Wilson, died December 26, 1991. Adams had been ill for about two years. Adams graduated from UNC-CH in 1956 and was employed at Wilson Memorial Hospital for 28 years. He was appointed Director of Pharmacy in 1964. First elected to the North Carolina Board of Pharmacy in 1972, he served as a member until 1990. He was elected president of the board four times. Active in all phases of institutional pharmacy practice, Adams received the North Carolina Society of Hospital Pharmacists "Pharmacist of the Year Award" in 1982.

Adams was a leader in the National Association of Boards of Pharmacy and was selected Honorary President in 1990. He was instrumental in the development of the NABPLEX Examination. He received the University of North Carolina School of Pharmacy Alumni Distinguished Service Award in 1990.

CORRESPONDENCE COURSE

UPDATE ON SUNSCREENS: PART 2

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss the therapeutic properties of sunscreen product ingredients, and list factors that affect their usefulness; and
2. report contemporary information relevant to OTC sunscreen products.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit an understanding of terms relevant to OTC sunscreen products and their ingredients;
2. choose an appropriate sunscreen when a specific request is made;
3. choose from a list information that best describes pharmacologic and toxicologic properties of sunscreen product ingredients ; and
4. select appropriate information to counsel patients concerning the correct use of sunscreens.

This lesson is the second part of a two-part series on sunscreens. Part I discussed ultraviolet light and the photodermatologic damage it causes to human skin. It defined the characteristics of specific wavelengths of ultraviolet radiation, and presented a summary of physiological effects to be expected following exposure to each of them. It also differentiated sunblocks from sunscreens, and explained the meaning of sun protection factor (SPF) and phototoxic protection factor (PPF) values.

Sunscreens — A Review

Not all that glitters is gold! There is strong indication that even brief exposures to the sun can harm the skin of some persons. And even though a brief exposure may not cause an acute burn or injury, the skin never forgets an injury! The greatest danger is that the chronic effects of overexposure are cumulative and persist for life. Indeed, there are over 40 identified pathologies that are known to be caused by exposure to solar radiation.

Table 1

Reasons for Protecting the Skin Against UVA Radiation

• - UV intensity varies with the latitude, season, and time of day, but UVA varies less than UVB.

• - The percentage of UVA in solar radiation is greatest in the early morning and afternoon.

• - At midday, 10 to 20 times more UVA than UVB reaches the earth's surface.

• - UVA augments the carcinogenic effects of UVB.

• - UVA causes histologic changes, including morphologic changes in Langerhans cells, and triggers release of inflammatory mediators.

• - UVA stimulates photosensitivity reactions, and hastens the photoaging process.

Of special importance is the recent finding that ultraviolet A (UVA) radiation is more damaging than previously believed, and has greater potential than UVB rays to cause serious health hazards. The current popularity of tanning salons has increased the potential for skin damage. Tanning lamps emit primarily UVA radiation. Each day more than one million Americans visit one of the more than 20,000 tanning salons in the U.S. Reasons for emphasis on protecting the skin against UVA rays are summarized in Table 1.

Substantivity

The ability of a sunscreen to bind with the stratum corneum and resist removal by sweating, exercising or swimming gives the product its substantivity value. Substantivity is a function of two variables: the sunscreen agent itself, and the vehicle. Products containing PABA or PABA esters are generally more substantive than those with other sunscreen agents.

FDA has established guidelines for substantivity. Claims that products are "water resistant" or "waterproof" mean that they will remain substantive to the skin and retain photoprotective efficacy for at least 40 minutes for the former, and at least 80 minutes for the latter, with moderate activity in water. The claim "resists removal by perspiration" is appropriate for both water resistant and waterproof sunscreens.

The vehicle used for a sunscreen product is extremely important. It largely determines the extent of dermal penetration, degree of absorption by proteins of the stratum corneum, and extent of loss of sunscreen with perspiring and swimming. The vehicle also greatly determines consumer acceptance of the product.

Sunscreen Agents

The ideal sunscreen should exhibit the following properties:(1)block most of the UVB and UVA radiation that reaches the skin; (2) prevent biochemical reactions that induce the sunburn reaction (i.e., block prostaglandin synthesis); (3) protect DNA of viable cells against changes than can lead to cytotoxicity; and (4) prevent photo-sensitivity reactions, photodermatoses, and photoaging, by filtering all UVA rays. There is a wide variety of photoprotection aids in the form of clear or milky lotions, gels, creams, or ointments to choose from (Table 2). By selecting a suitable sunscreen product, consumers can prevent many of the damaging effects caused by solar

Table 2

Representative Sunblock and Sunscreen Products

Product	SPF	Form	Ingredients
Bain de Soleil			
Body Silkening	25	Cream	Ethylhexyl p-methoxycinnamate Oxybenzone, Padimate O
Body Silkening Spray	20	Lotion	Same as above
Face Cream	25	Cream	Same as above
Coppertone			
Moisturizing Sunblock	25	Lotion	Ethylhexyl p-methoxycinnamate 2-ethylhexyl salicylate, Homosalate oxybenzone
Moisturizing Sunblock	15	Lotion	Ethylhexyl p-methoxycinnamate, Oxybenzone
Moisturizing Sunblock	8	Lotion	Same as above
Moisturizing Sunscreen	6	Lotion	Same as above
Moisturizing Suntan	4	Lotion	Same as above
Lite Tanning	4	Lotion	Ethylhexyl p-methoxycinnamate
Moisturizing Suntan	2	Oil	Homosalate
Lite Tanning	2	Oil	2-ethylhexyl salicylate
Dark Tanning Spray	2	Oil	Ethylhexyl p-methoxycinnamate
Hawaiian Tropic			
Baby Faces Sunblock	25	Lotion	2-ethylhexyl salicylate, Oxybenzone Octyl salicylate, Methyl anthranilate
15 Plus Sunblock	15	Lotion	2-ethylhexyl salicylate Oxybenzone, Methyl anthranilate
Sunscreen	10	Lotion	Padimate O, Oxybenzone
Protective Tanning	8	Lotion	Same as above
Dark Tanning with Sunscreen	4	Lotion	2-ethylhexyl salicylate, Methyl anthranilate
Photoplex			
Broad spectrum Sunscreen	15	Lotion	Padimate O, Butyl methoxydibenzoyl-methane
Presun			
39 Creamy	39	Cream	Padimate O, Oxybenzone
for Kids	29	Cream	Octocrylene, Oxybenzone, Octyl salicylate
29 Sensitive Skin Sunscreen	29	Cream	Same as above
23 Creamy	23	Cream	Padimate O, Oxybenzone
15 Sensitive Skin	15	Cream	Padimate O, Oxybenzone, Octyl salicylate
8 Creamy	8	Cream	Padimate O, Oxybenzone
Shade			
Sunblock	45	Lotion	Ethylhexyl p-methoxycinnamate Octocrylene, Oxybenzone
Sunblock	30	Lotion	Ethylhexyl p-methoxycinnamate 2-Ethylhexyl salicylate, Homosalate Oxybenzone
Sunblock	25	Gel	Same as above
Sunblock	15	Gel	Ethylhexyl p-methoxycinnamate, Oxybenzone
Sundown			
Sunblock Ultra	30	Lotion	Octyl methoxycinnamate, Octyl Salicylate Oxybenzone, Titanium Dioxide
Sunblock Ultra	25	Lotion	Same as above
Sunblock Ultra	24	Cream	Padimate O, Oxybenzone
Sunblock Ultra	20	Lotion	Octyl methoxycinnamate, Octyl salicylate Oxybenzone, Titanium dioxide
Sunblock Ultra	15	Cream	Same as above
Sunblock Ultra	15	Lotion	Padimate O, Oxybenzone, Octyl methoxycinnamate
Maximal	8	Lotion	Padimate O, Oxybenzone
Extra	6	Lotion	Same as above
Moderate	4	Lotion	Same as above

radiation.

PABA and its Esters. Sunscreen products that contain PABA esters have been the most widely used sunscreens in the U.S. A 5 percent solution of aminobenzoic acid (PABA) in 50 percent alcohol provides maximal sunscreen efficacy against all UVB radiation. However, it transmits most UVA rays. A major advantage is that PABA diffuses into the stratum corneum to bind with tissue protein in 30 minutes or less. The discovery of PABA esters was a significant advancement in modern sunscreen development. They can be incorporated into a wide array of product formulation. PABA esters are more acceptable than alcohol-based products because they are less irritating, more substantive, and more cosmetically elegant. Thus, consumers are more likely to comply with instructions.

Benzophenones. Benzophenones in common use include oxybenzone and dioxybenzone. These absorb light over a wide ultraviolet range. But the benzophenones are poorly substantive and require frequent reapplication.

Cinnamates. The effectiveness of cinnamate-containing products depends mainly on the activity of the vehicle to bind with the skin. Cinnamates do not bind with the skin and, therefore, have poor substantivity.

Salicylate Derivatives. Homosalate, ethylhexyl salicylate, and other salicylate derivatives have about one third the absorbance of PABA. Consequently, they must be used in high concentration, and are usually used in combination with other sunscreen agents. They do not bind to the skin, nor are they easily removed by sweating or swimming.

Dibenzoylmethane Derivatives. These comprise the newest group of marketed sunscreens. Dibenzoylmethane derivatives block radiation throughout the entire UVA waveband. Therefore, they are sometimes referred to as full-spectrum sunscreen agents. Recent marketing of butyl methoxydibenzoylmethane (Parsol 1789) in combination with padimate O (Photoplex) provides, for the first time, a full-spectrum sunscreen product effective in blocking solar energy throughout most of the UVB and the UVA range. Photoplex, therefore, provides greater protection against UVA radiation than other sunscreens previously available. This is especially important in the 360 to 400 nm range where much of the sun's damage is concentrated. Other commercially available absorbent sunscreens did not provide that protection. Clinical trials have demonstrated significantly greater sunscreen protection with Photoplex than with padimate O alone, butyl methoxydibenzoylmethane alone, or a combination of padimate O and other commonly used sunscreens.

Sunscreen Product Popularity

Many consumers use sunscreen products sporadically. Moreover, a vast number apparently do not understand fundamental points about them.

To illustrate, it has been documented that nearly two-thirds of consumers use a sunscreen *sometimes* during prolonged periods of sun exposure. But only one of seven *always* use a sunscreen product when exposed to the sun. Only one of seventy-two persons surveyed could specify the SPF value of the sunscreen product they used. And among products cited, some were actually emollients, rather than true sunscreens. A reason given by 20 percent of respondents who seldom, or never, used a sunscreen was their desire to acquire a tan. Only 9 percent said they rarely spend time in the sun.

Adverse Effects of Sunscreens

For the most part, sunscreen products are safe and seldom cause adverse reactions. Complications include erythema (redness), stinging and burning. Strangely, benzophenones and PABA derivatives are occasionally implicated in causing or aggravating photosensitivity reaction. Persons who are allergic to "caine"-type local anesthetics, thiazides, and sulfonamides, may experience cross reaction with PABA esters. Padimate O is considered to be the least involved of the PABA esters in initiating contact or cross sensitivity reactions.

Highly viscous products and those containing cinnamates and benzophenones are occasionally reported to aggravate acne.

Allergic contact dermatitis can also occur with fragrances and preservatives in OTC sunscreens. Vehicles such as triethanolamine stearate, or ingredients such as lanolin, almond oil, cocoa butter and antioxidants can also be sensitizing. Persons with a chronic photodermatosis condition (see Part I of this series) or past history of a topical eczema are most susceptible.

PABA may stain some clothing, especially white cotton, yellow to dark brown after exposure. PABA esters reportedly do not stain fabrics.

Advising Consumers on the Proper Use of Sunscreens

Nearly everyone who spends a lot of time in the sun is a candidate for sunscreen protection. There is strong reason to believe that many, if not most, consumers do not understand how to correctly use sunscreen products, thus affording pharmacists a great opportunity to counsel them.

Sunscreen products must be applied 30 to 60 minutes prior to exposure, to achieve maximum effectiveness. This allows time for the product to penetrate the skin and maximize its substantivity. Reapplication after swimming, sweating or exercise will assure that the product will be effective for the length of time as calculated from its SPF value.

For the past several years, several manufacturers have been playing an "SPF numbers game" by marketing products with 20, 30, and even higher SPF values. Many authorities agree that sunscreen products claiming to have SPF values greater than 15 (Table 3) are unnecessary for most people. They may be

Table 3

SPF Values and Skin Types

Skin Color/ Complexion	Skin Type	Susceptibility to Sunburn and Suntan	Recommended SPF to Avoid Sunburn
Very Fair	I	Always burns easily; never tans	15+
Fair	II	Always burns easily; tans minimally	15
Light	III	Burns moderately; tans eventually	10-15
Medium	IV	Burns minimally; always tans well	6-10
Dark	V	Rarely burns; tans readily	4-6
Black	VI	Never burns; becomes deeply pigmented	—

suitable for individuals with Type I skin, or others who experience photosensitivity reactions following brief encounters with ultraviolet light. Persons requiring higher SPF value products should not indulge in sunbathing or outdoor activities where they are exposed to the sun. The high SPF-value products may give a false sense of security, since SPF-15 products already block more than 93 percent of UVB radiation. The SPF value identifies the degree of protection against UVB, not UVA rays.

Persons with known photosensitivity liability should take extra precautions to minimize problems during times of prolonged exposure to sunlight. It would be best to discontinue use of cosmetics and highly perfumed and fragranced soaps. They should avoid drugs and chemicals that are known photosensitizers. If they must use one of them they should be extremely careful and protect their skin against ultraviolet rays.

The quantity of sunscreen applied is extremely important. Directions for tests to determine SPF values require application of 2 mg/cm^2 of skin. Many people use an insufficient amount of product, resulting in less than expected protection. A sunscreen product's perceived ineffectiveness may, therefore, not be due to product failure, *per se* as much as to improper application.

The following patient information will help pharmacists answer many of the most often asked questions about tanning and sunscreens.

1) Apply sunscreens liberally and evenly over all areas of the skin that will be exposed to sunlight. Begin 30 to 60 minutes before exposure. Allow it to dry before applying cosmetics or clothing. Reapply the sunscreen every 20 to 30 minutes or more often if swimming or perspiring heavily.

2) The SPF number does not specifically relate to the number of minutes or hours of exposure to the sun. It signifies a multiplication factor for the time an individual can stay in the sun, and it is different for every person. For example, an individual who would normally get a sunburn after 15 minutes in the sun could remain in the sun 4 times longer (1 hour) using an SPF 4 sunscreen product. With an SPF 8 product, the person can stay in the sun 8 times longer without experiencing a burn.

3) Sunscreen products claiming SPF values greater than 15 may offer little extra value over SPF-15 products. A pharmacist can discuss with you why this is so.

4) Reapplication of a sunscreen product does not protect skin beyond the daily time limit of the product as calculated from the SPF value. However, it does help prevent further burning.

5) Use a sunscreen product even on cloudy days. The sun's ultraviolet rays can still cause skin damage. Remember to use a sunscreen on all skin that will be exposed to the sun for even short periods if photosensitivity to drugs or chemicals is a problem.

6) Sunscreen products protect against burning. They do not promote tanning. Sunscreen users can tan without burning.

7) The difference between "waterproof" and "water-resistant" sunscreens is that water-resistant products must retain their efficacy for at least 40 minutes after submersion in water. Waterproof products must remain effective for 80 minutes after submersion in water.

8) A person who burns easily should minimize the time of exposure to sunlight during peak burning hours of 10 a.m. to 2 p.m. Reflective surfaces, especially concrete, sand, and water should be avoided.

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SEARLE

9) If the skin seems to "burn" more easily than normal when exposed to sunlight, the cause may be due to a reaction to a drug, or some other chemical used on the body. If discomfort persists, a physician should be consulted for further advice.

10) The nose, helix (top) of the ears, lips, cheekbone area, scalp of persons with thinning hair, and shoulders are particularly sunsensitive, and vulnerable to sunburn. Physical or chemical sunscreen products must be conscientiously reapplied often to these areas.

11) Itching, redness or a rash that develops while using a product are reasons to stop using it. A pharmacist or doctor can suggest an alternate product.

12) Since most individuals will experience nearly 70 percent of their total lifetime exposure to sunlight by 12 years of age, pre-adolescents should be protected from excessive exposure. Infants under 6 months of age should be kept out of direct sunlight. Sunscreens should always be used on children and adolescents while they are swimming or participating in other outdoor activities. It has been variously reported that a severe childhood sunburn increases the risk of skin cancer, later in life, by 50 to 70 percent.

13) Do not use alcoholic solution products on children under 12 years of age. They cause stinging, burning, and irritation.

14) Some of the physical sunblock products are marketed in a rainbow of bold, dashing colors. These vividly colored products offer no therapeutic advantage over non-colored products. However, they may encourage children and young adults to use the products more generously, and more often.

15) The type of clothing that best protects from sunburn is tightly woven, preferably colored, fabric.

16) Skin cancer is a significant problem in this country. There are over 600,000 new cases yearly, with approximately 7,000 deaths. Using a sunscreen product as directed can help reduce these figures. •

CORRESPONDENCE COURSE QUIZ

Sunscreens: Part 2

1. All of the following statements about substantivity are true EXCEPT:
   a. it refers to the ability of sunscreens to bind to the stratum corneum.
   b. it allows for resistance to the removal of the sunscreen by sweating, exercise or swimming.
   c. it is a function of the sunscreen agent, not its vehicle.
   d. it permits manufacturers to refer to their products as water resistant or waterproof.

2. Padimate O is a derivative of:
   a. aminobenzoic acid.
   b. benzophenone.
   c. cinnamate.
   d. dibenzoylmethane.

3. There is sufficient proof in the literature to warrant advising consumers to do all of the following when using a sunscreen EXCEPT:
   a. apply the product 30-60 minutes before sun exposure.
   b. reapply it after swimming or sweating.
   c. for type VI skin, use a product with an SPF value of 30 or higher.
   d. if you have problems with skin allergy, the unscented and preservative-free products would be best for you.

4. A consumer requesting a sunscreen that does NOT contain padimate O should be advised to select which of the following products?
   a. Bain de Soleil
   b. Photoplex
   c. Presun Creamy
   d. Shade Sunblock

5. Which of the following drugs or group of drugs is LESS likely to cross-react with PABA esters than the other three?
    a. Aspirin
    b. Procaine
    c. Sulfonamides
    d. Thiazides

6. Derivatives of which of the following provide the greatest substantivity?
    a. Aminobenzoic acid
    b. Benzophenone
    c. Cinnamate
    d. Dibenzoylmethane

7. Which of the following statements is true?
    a. Sunscreen agents not only protect against burning, they also promote tanning.
    b. The SPF number relates to a multiplication factor for the time individuals can be in the sun without burning and NOT the number of hours they can stay in the sun.
    c. There is no need to use a sunscreen on cloudy days because clouds filter the UV light that is generated by the sun.
    d. Reapplication of a sunscreen provides added protection beyond the daily time limit of the product's labeled SPF value.

8. Persons whose skin burns moderately and tans eventually are classified as having which of the following skin type?
    a. Type I
    b. Type III
    c. Type V
    d. Type VII

9. The ideal sunscreen should exhibit all of the following properties EXCEPT:
    a. prevent biochemical reactions that induce the sunburn reaction.
    b. block most of UVC and UVB, but not necessarily UVA.
    c. prevent photosensitivity reactions, photodermatosis and photoaging.
    d. protect DNA of viable cells against cytotoxic changes.

10. Which of the following provides the widest spectrum of protection against UVA radiation?
    a. Aminobenzoic acid
    b. Benzophenone
    c. Cinnamate
    d. Butyl methoxydibenzoylmethane

NORTH CAROLINA COMMISSION TO IMPLEMENT PHARMACEUTICAL CARE

North Carolina Pharmaceutical Association President Betty H. Dennis and North Carolina Society of Hospital Pharmacists President Cynthia T. Bishop have appointed the following pharmacists to the North Carolina Commission to Implement Pharmaceutical Care. The Commission is a continuation of the N.C. Pharmacy-in-the-21st-Century Conference held in 1990 and is a joint project of NCPhA and NCSHP. The charge to this commission is to identify and examine the barriers to the implementation of Pharmaceutical Care and develop strategies to overcome these barriers.

Thomas Hughes, *Chapel Hill, Chairman*
Ralph H. Ashworth, *Cary*
Jean B. Douglas, *Greensboro*
Fred M. Eckel, *Chapel Hill*
Jimmy S. Jackson, *Garner*
Martha W. Lyon, *Lexington*
Connie A. McKenzie, *Buies Creek*
Joe Norwood, *Chapel Hill*
Lori T. Setzer, *Winston Salem*
Mitchell W. Watts, *Concord*
Louis H. Weaks, *Charlotte*
Peggy C. Yarboprough, *Sims*

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CONTINUING PHARMACEUTICAL EDUCATION (CPE)

Sunscreens: Part 2

- Attach a mailing label from *The Carolina Journal of Pharmacy* or print your name and address and mail to CE Test, NCPhA, P.O. Box 151, Chapel Hill, NC 27514–0151
- Completed answer sheets may be returned on a monthly or less frequent basis for grading.
- **This is a member service. Non-member tests will not be graded nor CPE credit hours given.**
- NCPhA will maintain a copy of your completed CPE tests and upon successful completion of each program, will issue a certificate for one (1) hour of North Carolina Board of Pharmacy approved CPE credit.
- If more than two (2) questions are answered incorrectly, the test is failed. You will be given one (1) opportunity to submit a second answer sheet.

Please circle correct answer

1. a b c d
2. a b c d
3. a b c d
4. a b c d
5. a b c d
6. a b c d
7. a b c d
8. a b c d
9. a b c d
10. a b c d

Evaluation of material: Excellent Good Fair Poor

Name ______________________________

Address ______________________________

JUST A TEASER!

The 1992 Annual Convention of the North Carolina Pharmaceutical Association and Affiliated Auxiliaries is scheduled for Thursday through Sunday, May 21–24 at the beautiful and historic Pinehurst Resort and Country Club in the sandhills of North Carolina.

The Convention will open with the Awards Session on Thursday at 4:00 pm, at which we recognize pharmacists who have demonstrated excellence in the profession, civic activities or some other arena of service. In addition, we honor those pharmacists who are celebrating fifty years of service in the profession, by inducting them into the **NCPhA 50+ Club.**

If you were first licensed in North Carolina in 1942 or have a colleague who was, please contact the NCPhA office. We will be researching the Board of Pharmacy records but we might overlook someone. Thank you. The February issue of *The Carolina Journal of Pharmacy* will present a complete schedule of Convention activities and programs.

LETTER OF NOTE

Newton O. Fowler, Jr.
General Manager Philip Morris USA
PO Box 1098
Concord, NC 28025

Dear Newt,

In my years of civic and public service, one of the accomplishments in which I take greatest pride is my serving on the Mission Marlboro Team. I display with pride the photograph and plaque Philip Morris presented to us. At the time we were working on the project I only thought of the jobs a Philip Morris plant would bring to Cabarrus County. Since then I have come to appreciate the contribution your company has made, not only in jobs and the business those jobs have added, but in the very real contribution Philip Morris has made in the area of arts, culture, aesthetic beauty and in general improving the quality of life for the people of Cabarrus County. On the many occasions I have been invited to participate in these activities I have been honored but also felt an obligation to attend to show my continued support of your company by my presence.

As a health care professional, I have received some criticism for not speaking out against smoking in my newspaper column on health care matters or for continuing to sell tobacco products in my pharmacy, but I, as you, believe people should have the freedom to make a choice in such matters. I believe, as you do, the freedom to choose is what has made our country great and continues to make Philip Morris great. As long as I was able, I elected to fly in the smoking section even though I was a nonsmoker. I did so as a reminder to the airline that there were many of us who did want a choice, and in support of the contributions tobacco has made to North Carolina and to Cabarrus County.

I am therefore disturbed that your company has elected to not give your employees the freedom of choice in where they can get their prescriptions filled. One of my life long customers informed me that he could no longer get his prescriptions filled at my pharmacy but would have to drive to Concord and trade at Eckerds or Revco. There is confusion about when this goes into effect, now, or in the future, but the plan is in place to take away their freedom of choice!

I realize that you are not the person who made this decision, but I'll bet you know how to contact the person (s) who did. I also realize that part of the game is to make the best deal you can and do not fault your company for that, but when it involves a principal such as freedom of choice that is so much of what your business stands for, it seems to spit in the face of those of us who have supported you and the freedom to choose.

Sincerely yours,
Wm. Whitaker Moose, P.D.
Moose Drug
Mount Pleasant

LITTLE–NOTICED BOARD OF PHARMACY REGULATION

The North Carolina Board of Pharmacy has adopted the following regulation, effective October 1, 1991. It has been published in the North Carolina Administrative Code.

SECTION 2900–PRODUCT SELECTION

.2901– RETURN OF OUTDATED DRUGS

Adequate provision for return of outdated drugs both full and partial containers as provided in G.S. 90–85.28 (a) (5) means that drugs can be returned up to six months after the labeled expiration date for prompt full credit or replacement. A finding by the Board that a manufacturer does not meet this standard will cause that manufacturer's products to be ineligible for use in product selection.

☞ *This means that if a manufacturer DOES NOT have a return goods policy meeting these standards, products of that manufacturer MAY NOT be used in product selection in North Carolina.*

CLASSIFIED ADVERTISING

Classified advertising rates are 25 cents a word for members with a minimum of $5.00 per insertion and for nonmembers, classified ads are 50 cents a word with a minimum charge of $10.00 per insertion. Ads are accepted for a single issue or specific time period only. The closing date for ad orders is the first of the month preceding the issue in which you are requesting insertion. Payment for ad orders will be billed. Names and addresses will be published unless an ad number for a blind ad is requested. In replying to blind ads, send to Ad ( ), c/o NCPhA, P.O. Box 151, Chapel Hill, NC 27514. Telephone 800-852-7343 or 919-967-2237.

PHARMACIES FOR SALE

PHARMACY FOR SALE: Don't miss an exceptional opportunity to become your own boss in a professional atmosphere. An established prescription-oriented pharmacy located in the Winston-Salem area is offered for individual ownership. This opportunity will allow you the freedom to cut your hours, spend evenings, Sundays and holidays with your family and to practice your profession the way you were taught. For detailed information, call John Aumiller 800-325-1397.

RELIEF PHARMACIST POSITIONS

PharmaSTAT Inc., PHARMACY RELIEF SERVICES: Pharmacists available statewide for your pharmacy needs 800-252-STAT.

Let **RXPH**armacy Services, Inc. accommodate all your pharmacy needs. For assistance with **RELIEF PHARMACISTS, RELIEF TECHNICIANS,** and **PERMANENT PLACEMENT** call Anita at 800-722-**RXPH** (7974).

COMMUNITY PHARMACIST POSITIONS

PHARMACIST WANTED: Kerr Drug Stores has positions available for pharmacists in the Morehead City area. Kerr Drug offers opportunity for growth into store management. Excellent benefits. Send resume to: George Smith, P.O. Box 61000, Raleigh, NC 27661 or call 919-872-5710.

PHARMACIST OPPORTUNITIES: Excellent environment in which to demonstrate professional skills. Positions available for the very best in many locations in the Carolinas. Excellent compensation and benefit programs including generous bonus and profit sharing. Send resume to Nick Martino, Eckerd Drug Co., P.O. Box 31243, Charlotte, NC 28231, or call 704-371-8242.

PHARMACISTS WANTED: Revco is actively seeking full-time pharmacists in various Piedmont and western N.C. locations. We offer a complete benefit package including medical, dental, life and disability insurance, profit sharing, Rx bonus and continuing education. Call Lori Setzer at 704-634-1879 or Joe Feutz at 704-253-4078.

Community Pharmacist Positions

PHARMACIST WANTED: Full or part-time. Retail management experience preferred. Ownership option available. Excellent working conditions, no nights or Sundays. Send resume to P.O. Box 29, Reidsville, NC 27323, or call Arnold Britt at 919-349-8221.

Miscellaneous

DOCTOR OF PHARMACY (PHARM.D.): Would you like to obtain a Pharm.D. degree? If you are a recent B.S. Pharmacy graduate, contact the Director of Admissions, Campbell University School of Pharmacy, Buies Creek, NC 27506 or Call 800-334-4111, Ext. 3101.

Want a charcoal sketch of yourself? Satisfaction guaranteed. This would make a gift. Send only $20.00 and a picture to Mrs. Betsy Clinard, 1609 Emorywood Dr., Charlotte NC 28210.

FOR SALE: Office space in Nags Head, N.C. 1296 square ft. Space was utilized successfully as a pharmacy four years ago. Landlord is very eager to attract a licensed pharmacist who is interested in living in one of the most beautiful and fastest growing areas in N.C. Please contact Emily Ausband, P.O. Box 1586, Nags Head, N.C. 27959.

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KAPPA EPSILON'S Alpha Rho Chapter at Campbell University will be hosting Province A's Biennial Meeting, April 10-12, 1992. For further information, contact chapter advisor Dr. Constance McKenzie at 800-334-4111 ext. 3501.

COMPUTER FOR SALE: Triad Pharmacy System software with Texas Instrument Business-Pro Hardware MSDOS 3.1 (1 work station w/printer) $18,275 new. Will sell for $2650. Call 704-256-2181, M,W, F, S.

FOR YOUR INFORMATION

Many times pharmacist members of the North Carolina Pharmaceutical Association receive mailings from insurance companies, car rental agencies and others promoting their wares or services. Often these pharmacists call the NCPhA office to ask if we have endorsed these companies or if we have sold our membership list to someone who is doing a mass mailing to pharmacists in the state.

NCPhA does not sell its mailing list of members. We do make it available to organizations such as "The Pharmacist Letter" or perhaps other state pharmacist associations who are informing our members about a professional service or continuing education program that may be a benefit. We respect your confidentiality!

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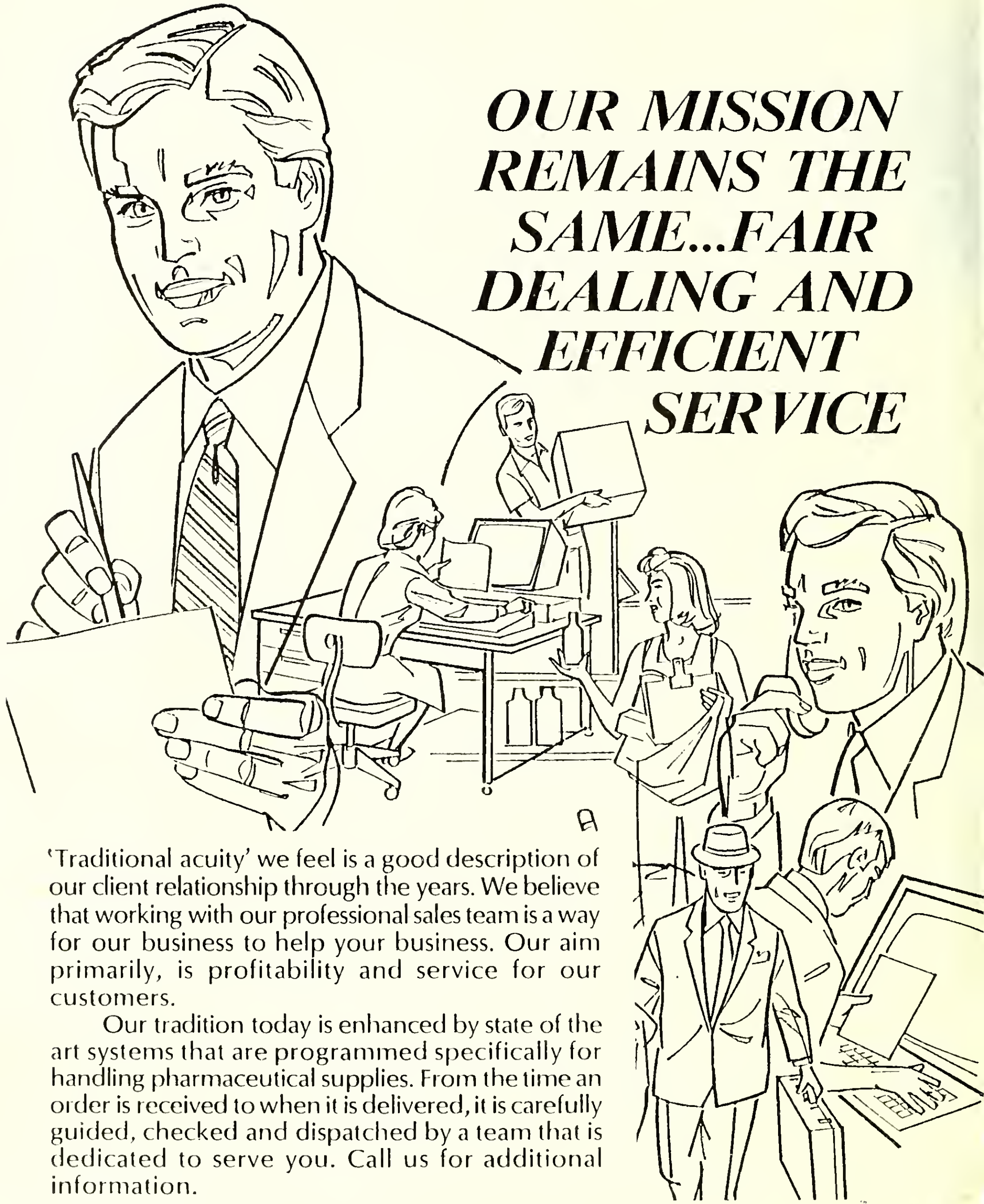

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THE CAROLINA
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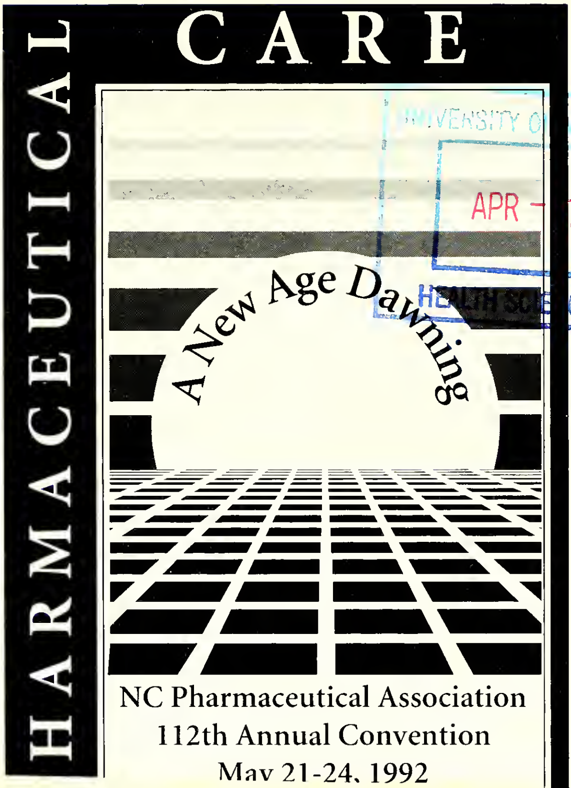
FEBRUARY 1992 VOLUME 72 NUMBER 2



NC Pharmaceutical Association
112th Annual Convention
May 21-24, 1992

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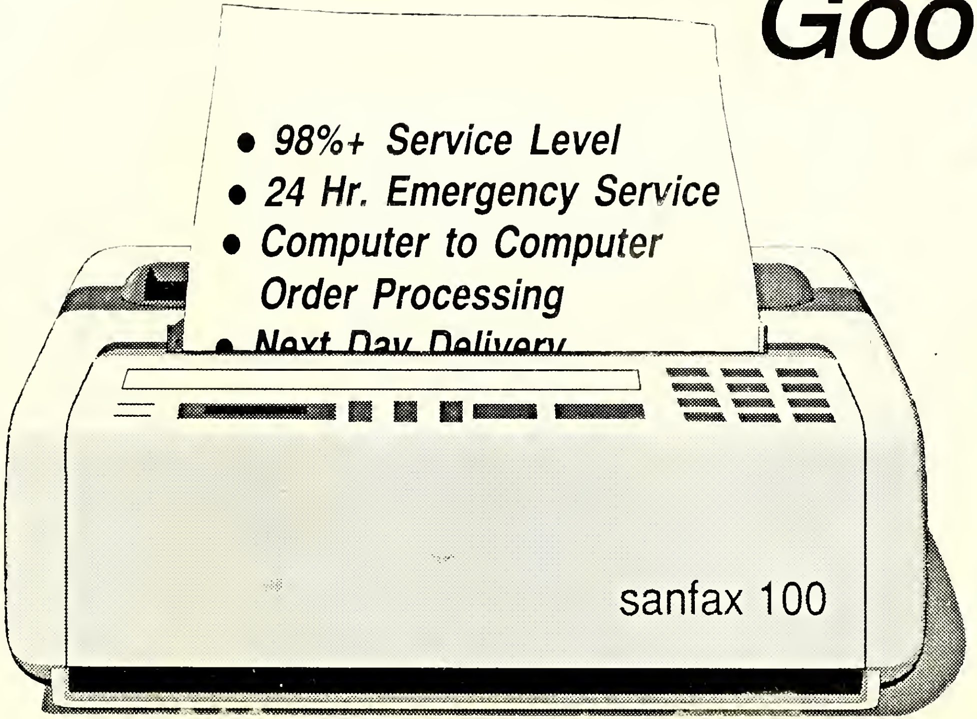
Complete Convention Information
See page 5

Good News Travels Fast!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THE CAROLINA
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Important figures in diabetes care

7

Diabetes is the **No. 7** cause of death in the US[1]

1

Diabetes is the **No. 1** cause of new blindness in persons aged 20-74[1]

Pharmacists see patients with diabetes **5** times more often than do physicians. These customer's spend 3 to 8 times more annually in the pharmacy than persons without diabetes.[2]

Lilly

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46285

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Your Lilly sales representative will visit you soon with information on a number of services and materials we can offer you and your customers with diabetes.

1. *Diabetes Surveillance, 1980-1987.* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

1992 ANNUAL CONVENTION

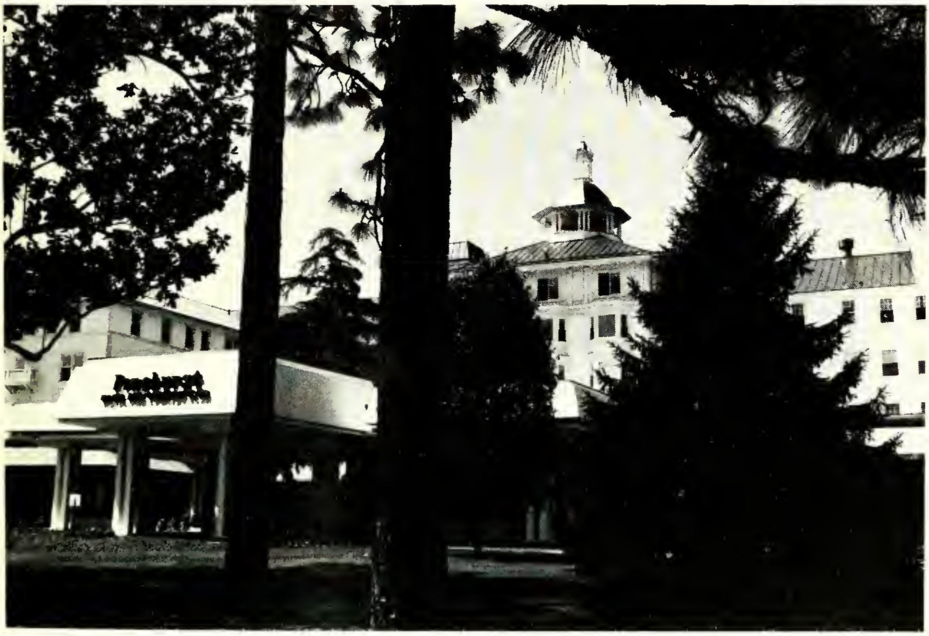
OF THE

NORTH CAROLINA PHARMACEUTICAL ASSOCIATION
THE WOMAN'S AUXILIARY
THE TRAVELING MEMBERS' AUXILIARY

PINEHURST RESORT AND COUNTRY CLUB
PINEHURST, NORTH CAROLINA
MAY 21 – 24, 1992

"PHARMACEUTICAL CARE, A NEW AGE DAWNING"

Come to the beautiful Sandhills of North Carolina, to one of America's favorite vacation sites, and enjoy the hospitality, warmth and scenery. This convention promises to be an outstanding meeting, with important educational offerings (all 10 hours are ACPE-approved), golf at noted Pinehurst # 2 and # 7 courses, tennis and other recreational activities such as lawn croquet. Shopping in Pinehurst may interest some attendees. The Woman's Auxiliary has arranged for Nancy Brinker, founder of the Susan G. Komen Institute of Dallas, Texas to speak to a joint meeting of all registrants on Friday morning, with everyone invited including interested townfolk. The Exhibit Program this year is special, featuring over 45 booths and held on Saturday night, with a sumptuous, elegant buffet supper, a strolling magician–in-residence and a staged magic show. More information is on the following pages •



The Pinehurst Resort and Country Club, Pinehurst, North Carolina

PERSONALITIES OF THE 112TH ANNUAL CONVENTION

Suzan Maddox, President
Woman's Auxiliary

Betty Dennis, President
NC Pharmaceutical
Association

Photograph
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Junior Little, President
Traveling Members'
Auxiliary

Walter Fitzgerald, Speaker

Vicki Reid, Speaker

Dan Teat, Speaker

Nancy Brinker, Speaker

Bob Sheets, Prestidigitator

Bill Tindall, Speaker

CONVENTION SCHEDULE

112TH ANNUAL MEETING

NORTH CAROLINA PHARMACEUTICAL ASSOCIATION AND AFFILIATED AUXILIARIES

Thursday, May 21

8:00 am–5:00 pm	**UNC School of Pharmacy** **Practitioner–Instructor Workshop**
3:00–6:00 pm	**Registration Desk Open**
5:00–6:00 pm	**NCPHA AWARDS SESSION** Betty Dennis, *presiding*
6:00–7:00 pm	**PRESIDENTS' RECEPTION** honoring Dean Tom S. Miya Presidents of NCPhA, Woman's Auxiliary, and Traveling Members' Auxiliary and Award Recipients
7:00–10:00 pm	**OPENING BANQUET** Betty H. Dennis, NCPhA President, *Presiding* Vicki Reid, keynote speaker **"What You See Is What You Get"** *supported by Upjohn*

Friday, May 22

7:00–8:30 am	**Christian Pharmacists Breakfast**
8:00–9:00 am	**T.M.A. Foundation Breakfast**
8:00 am	**Registration Desk Open**
8:30 am	**1st NCPhA GENERAL SESSION** Henry L. Smith, President Elect, *Moderator* **Rite of the Roses** Mr. and Mrs. Jimmy Jackson **President's Address** Betty H. Dennis **Committee Reports** Nominations, Resolutions and State Legislative Committees **Annual Report of the N.C. Board of Pharmacy** David R. Work, Executive Director

	1st NCPhA GENERAL SESSION, *Continued*
10:00 am–12:30 pm	**COMBINED SESSION OF NCPhA, WOMAN'S AUXILIARY, T.M.A** **"Importance of Taking Health Care Into Your Own Hands" • • • 1.0 ACPE hrs. • • •** Nancy Brinker, *Founder* Susan G. Komen Breast Cancer Foundation *supported by Miles Inc., Burroughs Wellcome, ICI Pharmaceuticals, Smith Kline & Beecham* **"Update On Breast Cancer" • • •1.0 ACPE hrs. • • •** Celeste Lindley, Associate Professor UNC School of Pharmacy *supported by Glaxo Inc.*
Refreshment Break Sponsored by N.C. Mutual Wholesale Drug Company	
12:30 pm	**Woman's Auxiliary Luncheon** *sponsored by Glaxo Inc.*
12:30 pm	**Practitioner Instructor Luncheon**
Afternoon	**GOLF TOURNAMENT** *sponsored in part by Owens–Brockway, Glaxo Inc. and Burroughs Wellcome Company* **TENNIS TOURNAMENT** *sponsored by Jefferson Pilot* **WOMAN'S AUXILIARY CROQUET** **WOMAN'S AUXILIARY COOKING DEMONSTRATION**
2:00 pm–4:00 pm	**WORKSHOP • • •2.0 ACPE hrs. • • •** **"Managing the Patient on Cancer Chemotherapy"** Celeste Lindley, Associate Professor UNC School of Pharmacy *supported by Glaxo Inc.* Rebecca Finley, Associate Professor University of Maryland, Baltimore
9:00 pm	**T.M.A. SPONSORED DANCE** **featuring** *Second Chance of Durham*

Saturday, May 23

7:00 am	**Woman's Auxiliary Walk–a–Thon**
7:00–8:30 am	**PharmPAC Breakfast** Representative Dennis Wicker, featured speaker N.C. House Majority Leader
8:30 am–12:30 pm	**2nd NCPhA GENERAL SESSION,** "Pharmacist/Patient Consultation Program" **• • • 4.0 ACPE hrs. • • •** William Tindall, Executive Director Academy of Managed Care Pharmacy Dan Teat, Director, Continuing Education Campbell University School of Pharmacy *sponsored by National Health Care Operations—* *A Division of Pfizer Pharmaceuticals*
9:00 am–5:00 pm	**NC Board of Pharmacy Exam Review**
10:00 am	**Woman's Auxiliary Meeting**
11:00 am	**Traveling Members' Auxiliary Business Meeting**
12:30 pm	**Woman's Auxiliary Luncheon, Fashion Show, and Installation of Officers** *sponsored by Burroughs Wellcome Company*
Afternoon	**Golf, Tennis, Croquet, and Lawn Bowling** *(on your own)*
2:00 pm–4:00 pm	**WORKSHOP • • •2.0 ACPE hrs. • • •** **"The Pharmacist's Duty to Warn: Evolving Professional and Legal Issues"** Walter Fitzgerald, J.D., R.Ph., Associate Professor University of Tennessee *supported by an educational grant from Searle*
6:00 pm	**Reception**
7:00–11:00 pm	**EXHIBITION SHOW AND BUFFET DINNER featuring special entertainment and periodic prize drawings**
11:00 pm	**EXHIBIT SHOW GRAND PRIZE DRAWING**
11:00 pm	**ICE CREAM PARTY**

Sunday, May 24

7:30 am	**BREAKFAST AND INSTALLATION OF OFFICERS**
9:00 am–12:30 pm	**3rd NCPhA GENERAL SESSION**

Henry L. Smith, 1992–93 President, *Moderator*

Discussion & Voting on:

- **Proposed Resolutions,**
- **Nominations for NCPhA Candidates for Office**
- **Constitution & Bylaws Amendments**

Annual Reports:

- **Campbell Univ. School of Pharmacy**
  - Ronald W. Maddox, Dean
  - Bill McKelvey, ASP President
- **UNC School of Pharmacy**
  - Tom S. Miya, Dean
  - Kristin McKeithan, ASP President

Reports:

- **Time & Place Committee**
- **Convention Registrar**

Adjournment of the Annual Meeting

FRIDAY AFTERNOON WORKSHOP LEADERS

Celeste Lindley, Speaker

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Available

Rebecca Finley, Speaker

INVESTIGATIONS SUGGEST PATTERNS FOR IMPAIRMENT IN HEALTH CARE PROFESSIONALS

By R. Keith Bulla, Special Agent in Charge, State Bureau of Investigation.

Since 1974, North Carolina has lost far too many health care professionals to an occupational risk, substance abuse. Medical, pharmacy, and nursing schools are not preparing students for coping with their problems. Everything is directed at curing the other person's problems.

For the last ten years the Diversion Investigation Unit (DIU) of the State Bureau of Investigation has been trying to determine how or why certain people abuse drugs. After fifteen years of working with health care professionals, certain patterns have been identified. The work began with nurses under investigation for diversion of controlled substances.

As the investigation centered on an individual, an interview was conducted. The questions were designed to identify the stages which led to the diversion. Often the reply was, "I was just trying to cope." But why was this group turning to prescription drugs? Then the questions were directed at the first exposure to prescription drugs.

The pattern begins. The vast majority had their first exposure through legitimate medical needs, most often surgery or treatment for back pain or migraine headaches.

The next identified stage is treatment by an over-prescribing physician. This well meaning physician gives the patient too much for too long and allows the patient to self-medicate. It is during this stage that the patient may record a "mental tape" of the side effects of the drug. As we study the abuse of drugs, we find they are abused for their side-effects, not the therapeutic effect.

The patient has "recorded" the side effect. The original problem may now be corrected and the patient may go for an extended period without using the drug. There is no drug problem at this time.

Months or perhaps a year or two later, the "patient" begins to have problems at work. Job stress, burn-out, depression or any combination begins to affect the day-to-day life of the individual. For some, the problem develops in the home or family. Whether it begins at home or at work, without help the problem will soon affect both.

Very often the most pressing need of the patient is a good night's sleep. In the frustrating search for much needed sleep, the mental tape is replayed. "The side effect is a peaceful sleep." A return to the medicine cabinet and the person receives some relief. One good night's sleep is wonderful, just a few more and all will be better. A pattern or "misuse" has begun. The person has taken the prescription drug not for the therapeutic effect but for its side effect.

If this misuse continues, it can quickly lead to abuse and create a demand while an individual tries to cope with problems. Now, this troubled person begins to look for a supply, and we call this person an impaired professional.

The next stage involves prescription forgery or alteration of prescriptions. This is often a very short stage, which is the beginning of violating the controlled substance act.

Soon, the person turns to doctor shopping, the fastest growing drug source in the country. Doctor shopping is easy for some nurses. Every day they are in contact with several physicians. Simply complain of headaches, backache, or other symptoms, just remember—don't ask the same physician too often. Next, we see the person going to multiple physicians' offices, always trying to obtain a prescription. By this stage, the person may feel they need the prescription just to maintain "normal" functioning. The amount and frequency of abuse tends to increase. The amount taken daily often far exceeds the recommended therapeutic level.

By this stage, the person has many times begun to exhibit some signs of abuse, but it is not recognized by peers. Most health care professionals have not been trained in substance abuse recognition. Others may have concerns, but find it very difficult to confront a peer without "evidence."

The last stage is the one which usually triggers outside reviews and intervention—diversion from stock. The nurse may have an order for 75mg of Meperidine for a patient. The nurse may have administered 50mg to the patient, and instead of wasting the other 25mg, will self-administer them. Later, that same nurse may reduce an authorized patient dose or even dilute or completely substitute the prefilled syringe on the shelf and leave it for an unsuspecting nurse to use. This last form of diversion occurs many times each year throughout North Carolina hosptials. The nurse did not set out to abuse drugs, but was trying to cope with a problem without help and without the skills needed to solve the problem.

This model was developed from investigations with nurses; we now see that other health care professionals follow a similar pattern. An alteration of this model occurs when a person enters at the abuse stage through "recreational" use of street drugs and then turns to the prescription drugs. They start with an entirely different motivation for their drug use.

North Carolina cannot afford to lose all those professionals developing problems with substance abuse. The solution is a combination of education, treatment and enforcement *all* working together.

Reprinted from Epikrisis, *the newsletter for the Governor's Institute on Alcohol and Substance Abuse, Inc.* ●

LICENSED FOR 50 YEARS OR MORE?

If you have been licensed as a pharmacist for 50 years or more–licensed in 1942 or earlier–you are eligible for induction into the NCPhA Fifty Plus Club. Those qualifying will be recognized and inducted during the Awards Program of the 112th Annual Convention in Pinehurst, on Thursday afternoon, beginning at 5:00 pm. A reception honoring the award recipients will immediately follow the ceremony. Family and friends are cordially invited to this induction.

For more information, contact the NCPhA office in Chapel Hill at 800-852-7343. Ask for Terri Little.

CALL FOR RESOLUTIONS

Resolutions from NCPhA members may be submitted for discussion, review and action at the Annual Convention in Pinehurst. Your resolutions help establish NCPhA policy, planning and direction. Each resolution is reviewed in advance of the meeting by the NCPhA Resolution Committee for form and suitability. These resolutions are then presented by the Committee to the floor of the Convention during the First and Last General Sessions.

You should submit your resolution in writing (it does not have to be in final form) to:

Lori T. Setzer, Chairman
NCPhA Resolutions Committee
P.O. Box 151
Chapel Hill NC 27514-0151

TENTATIVE MEETING DATES OF NATIONAL PHARMACY ORGANIZATIONS

(Thanks to Stan Stewart – Maine)

1992
NACDS – Annual Mtg – April 25 – 29, 1992, Maui, HI
ASCP – Mid Year Conf – May 13 – 16, 1992, Tuscon, AZ
NARD National Leg – May 17 – 19, 1992, Grand Hyatt, Washington, DC
NARD RxExpo – May 27 – 30, 1992, New Orleans, LA – Memorial Day 5/25
ASHP – 49th Annual Mtg – May 31 – June 4, 1992, Washington, DC
NACDS Marketplace Conf – June 28 – July 1, 1992, New Orleans, LA
NACDS – Pharmaceutical Conf – Aug 29 – Sept 3, 1992, Chicago, IL
NARD 94th Annual Convention, Oct 25 – 29, 1992, Seattle, WA
ASCP Annual Meeting – Nov 11 – 15, 1992, Orlando, FL
ASHP – Mid Year Clinical Mtg – Dec 6 – 10, 1992, Orlando, FL

1993
APhA, March 20 – 24, 1993, Dallas, TX
NACDS – Annual Mtg – April 17 – 22, 1993, Palm Beach, FL
NARD – Nat'l Leg Conf – April 25 – 27, 1993, Washington, DC
ASCP Mid Year Conf – May 12 – 15, 1993
NARD – RxExpo – May 27 – 30, 1993, Orlando, FL
ASHP – Annual Mtg – June 6 – 10, 1993, Denver, CO
NARD 95th Annual Convention – Oct 24 – 29, 1993, Indianapolis, IN
ASCP Annual Meeting – Nov 10 – 14, 1993, New Orleans, LA
ASHP Mid Year Clinical – Dec 5 – 9, 1993, Atlanta, GA

1994
APhA, March 19 – 23, 1994, Seattle, WA
NACDS – Annual Mtg – April 23 – 28, 1994, Palm Beach, FL
ASCP Mid Year – May 11 – 14, 1994
NARD Nat'l Leg Conf – May 15 – 17, 1994, Washington, DC
ASHP – Annual Mtg – June 5 – 9, 1994, Reno, NV
NARD 96th Annual Convention, Oct 16 – 20, 1994, Boston, MA
ASCP Annual Meeting – Nov 9 – 13, 1994, Boston, MA
ASHP – Mid Year Clinical Mtg – Dec 4 – 8, 1994, Miami, FL

1995
APhA, March 18 – 22, 1992, Orlando, FL
Fall Mtg – Sept 8 – 10, 1995 – Samoset (LD – 4, R – 25, YK 10/4)
NARD 97th Annual Convention, Oct. 15 – 19, 1995, Las Vegas, NV
ASCP Annual Meeting – Nov 15 – 19, 1995, San Francisco, CA

1996
NARD – 98th Annual Meeting – October 13 – 17, 1996, New Orleans, LA

1997
NARD – 99th Annual Meeting – October 19 – 23, 1997, Denver, CO

1998
NARD – 100th Annual Meeting – Oct 18 – 22, 1998, St. Louis, MO

1999
NARD – 101st Annual Meeting – October 24 – 28, 1999, Las Vegas, NV

2000
NARD 102nd Annual Meeting – October 15 – 19, 2000, San Antonio, TX

TRIPLICATE PRESCRIPTIONS

As earlier reported in this newsletter (*Rx Ipsa Loquitur*), the state of New York passed legislation to try to limit the use of benzodiazepines through the use of triplicate prescription forms. This was an unusual move by the state of New York in that most states that have adopted triplicate prescription programs have restricted their use to Schedule II prescriptions.

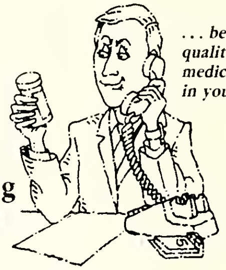
There are reports that New York's plan may have backfired. A November 6, 1991 article in the *Journal of American Medical Association* (*JAMA*) reports that while the use of benzodiazepines has been reduced, there has been an undesirable increase in the prescribing of less acceptable medications (presumably as an alternative for benzodiazepines).

The New York law limits most benzodiazepine prescriptions to a thirty day supply with a new order required for additional medication. Pharmacists are required to forward a copy of each prescription to the state Department of Health. Data which have been collected since the implementation of the new law show up to a 60% reduction in the use of benzodiazepines. The authors of the *JAMA* article find it difficult to believe that over 60% of the prescribing of this class of drugs prior to the enactment of the law was inappropriate. They write "the alternative sedative-hypnotic medications are less effective, more likely to be abused, and more dangerous in overdoses than benzodiazepines."

This article is reprinted from the December 1991 issue of Rx Ipsa Loquitur*, a publication of the American Society for Pharmacy Law*

USP

Drug Product Problem Reporting Program



. . . because the quality of their medications is in your hands!

The North Carolina Pharmaceutical Association is cooperating with the USP in presenting the **USP Drug Product Problem Reporting Program**

The USP DPPR is relying on your observations of poor product quality, therapeutic ineffectiveness, packaging and labeling problems, and possible product tampering to improve the quality of prescription and OTC drug products in the marketplace. The USP program is a private, non-governmental program designed to immediately inform participating product manufacturers and the FDA of potential health hazards and defective products based on the report *you* submit.

Reports may be submitted in writing using a USP report form or by calling USP toll free. The manufacturer or the FDA may contact you directly to discuss your concerns and USP will forward to you any information we may receive.

Your reports will be computerized and correlated with reports from other health professionals. This will allow for trend analysis of medical products on the market.

Your input is needed to help provide a complete picture of current trends for a more accurate evaluation of these products. Reports of problems experienced in your practice will help to provide practical input into the improvement of compendial standards in the *USP/NF* or drug information monographs in the *USP DI*.

We hope you will continue to support the USP Drug Product Problem Reporting Program your input can make a difference!

1-800-638-6725

AMERICANS WITH DISABILITIES ACT OF 1990
PART I: EMPLOYMENT ISSUES

The Americans with Disabilities Act (ADA), signed by the President on July 26, 1990, provides for sweeping changes on behalf of disabled Americans in the areas of employment, public services, public accommodations, services operated by private entities, and telecommunications. This is the first of a two-part article on ADA issues affecting pharmacists. This article addresses pharmacists as employers, and the second article will address accessibility requirements for pharmacies that sell to the public.

Under the ADA, an employer may not discriminate against a qualified individual with a disability. The prohibition of discrimination extends to all aspects of employment, such as job application procedures, hiring, promoting, terminating, compensating, seniority, leaves of absence, sick leave, fringe benefits, training, and social and recreational activities.

For the ADA to apply, an employer must be engaged in an industry affecting commerce. During the period from July 26, 1992 through July 25, 1994, the ADA will apply only to employers with 25 or more employees employed every working day in 20 or more calendar weeks in the current or preceding calendar year. After July 25, 1994, the ADA will apply to employers with 15 or more employees every working day in 20 or more calendar weeks in the current or preceding calendar year.

An individual with a disability is an individual who:

(1) Has a physical or mental impairment that substantially limits one or more of the major life activities of such individual;
(2) Has a record of such an impairment; or
(3) Is regarded as having such an impairment.

Denise Stanford Haskel
An associate with the law firm of Bailey & Dixon in Raleigh.

A physical or mental impairment would include any physiological disorder or condition, cosmetic disfigurement, anatomical loss affecting certain body systems, or any mental or psychological disorder. A major life activity includes such functions as caring for oneself, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

Individuals currently using illegal drugs or using legal drugs illegally are not considered disabled. However, an individual may be considered disabled if he has successfully completed or is participating in a supervised drug rehabilitation program and is no longer illegally using drugs. An employer is not prohibited from using drug testing to determine if an individual is illegally using drugs. The term disability also does not include sexual behavior disorders, compulsive gambling, kleptomania, pyromania, or psychoactive substance use disorders resulting from the current illegal use of drugs.

An employer will violate the ADA if he fails to make "reasonable accommodations" for the known physical or mental limitations of an otherwise qualified applicant or employee, unless he can show that the accommodation would impose an "undue hardship" on his business operations. A qualified applicant or employee is an individual with a disability who possesses the skill, education, and experience requirements for the job and who can perform the "essential functions" of the job with or without reasonable accommodation.

"Essential functions" of a job are those duties that are fundamental to the position sought. A "reasonable accommodation" would include modifying existing facilities so that they are accessible to and usable by disabled employees; job restructuring; modifying work schedules, equipment, examinations, and training procedures; and other similar accommodations for the disabled. An accommodation would impose an "undue hardship" on the employer if the accommodation is significantly difficult or expensive.

The Equal Employment Opportunity Commission has published regulations implementing the employment provisions of the ADA. These regulations will become effective on July 26, 1992.

The ADA will have a far-reaching impact on employers and their employment practices. Pharmacists need to be aware of the protections for the disabled under the ADA should an individual with a disability apply for a position with the pharmacy.

This is the third in a bimonthly series of articles concerning general legal topics. They are prepared by the law firm of Bailey & Dixon in Raleigh, who provide comprehensive services in administrative law, litigation, government relations and commercial transactions. The Journal *solicits your comments and suggestions for future articles.* ●

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TO THE EDITOR

On Saturday, January 26th, I received a contract from Blue Cross/Blue Shield of North Carolina that stated prescriptions for their subscribers would be paid for by a formula paying pharmacists LESS than what NC Medicaid pays for Welfare prescriptions. BC/BS alleges that its formula of AWP minus 10% plus a fee of $5.04 is equivalent to NC Medicaid formula of AWP minus 10% plus a fee of $5.60! Incredible!

If BC/BS really believed its formula was the same as NC Medicaid, why did it go to such trouble to create an alternative formula! Why not adopt the existing Medicaid formula? Ironically BC/BS of Virginia sent a proposal a day later with the same formula as NC Medicaid. Strange that our cousins across the line to the north know the legal and practical lay of the pharmaceutical turf in North Carolina better than BC/BS of Durham. Last year BC/BS of NC did a unilateral change in the format of its insurance claims for prescription drugs. Neither policy holders nor practitioners in the field had advance notice. A lot of time and energy was wasted in the process. But did BC/BS of North Carolina learn anything from that 1991 escapade? No! This time it involves MONEY from prescriptions. Instead of consulting local pharmacists to see if any of them really believe a fee of $5.04 and a fee of $5.60 are the same, BC/BS just asserted that to be the case and started the mails. Perhaps BC/BS of NC sees things this way. Medicaid fee is $5.60. But if Medicaid Rx's are refilled in the same month, they do not receive a fee. Assume 7% of Medicaid prescriptions per month involve refills with no fee. That drops the effective fee $.28 to $5.32 from $5.60.

But if BC/BS had consulted pharmacists in the field they would know that $5.32 is not the same as $5.60 in the world of NC Medicaid. BC/BS of NC goes on to require phone calls for each Rx which will probably average $.12 each. Because of that requirement (contract Item 3.5) $5.32 drops to $5.20. By contrast, NC Medicaid requires neither a loss of $.12 per Rx nor the waste of time involved per Rx as BC/BS will.

BC/BS asserts that its MAC list is higher than the Federal MAC list. But for how long will that be true? Who among us has the time to compare each of their MACS with the Federal MAC? And even if we did have that time, and even if we accept their assertion that this adds $.40 per Rx (i.e. $5.20 + .40=$5.60), whose Medicaid prescription business is made up solely or even predominantly of MAC drugs? The majority of my Medicaid practice is not for MAC prescriptions. So clearly the BC/BS formula cannot equal or exceed the Medicaid reimbursement at present. NC Medicaid has consistently said that if a pharmacist accepts any lower price for any one prescription from a third party source than it gets from Medicaid, then NC Medicaid requires billing of that prescription and all Medicaid prescriptions with that same lower formula.

BC/BS of NC implies that its "averaging" approach is the equivalent of NC Medicaid. It isn't now and it can't be. In effect BC/BS of NC is asking pharmacists who participate in the NC Medicaid program to break the law by agreeing to accept a lesser fee from BC/BS of NC.

Even Virginia recognizes the situation and so revised their approach recently. They changed their position of the prior year because Carolinians stood tall. Will it take BC/BS of NC a year to learn that same lesson? If BC/BS of NC wanted a program the financial equivalent of NC Medicaid, common sense says "adopt the NC Medicaid formula—and add $.12 for phone calls"!

I remember that it took a lot of work to get the Rx fee increased to $5.60 in the last session of the General Assembly. In a recessionary climate requiring $600 million in program cuts and tax increases of $600 million to balance the budget, a small miracle occurred. The Medicaid prescription fee went to $5.60. To accept a fee less than the medicaid fee of $5.60

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"THE POWER PHARMACIST"

Necessity, they say, is the "mother of invention." So, faced with the wholesale slaughter of a community necessity—thousands of local pharmacies—by third-party marauders and government agencies, the profession has invented a new breed, the Power Pharmacist.

The Power Pharmacist has broken with the past and embarked on a new mission: building dependencies.

He or she will do anything to make a patient dependent on his or her pharmacy—whether for prescriptions, OTC specialities, lottery tickets, newspapers, gardening tips, etc.

The Power Pharmacist is an active member of his or her local and state pharmacy association

Essential equipment in the Power Pharmacy is a computer with modem and word-processing software (a desirable option is desktop publishing software), and a fax machine. These facilities make it a simple matter to issue news releases electronically to local media, and to conduct direct mail marketing/public relations campaigns.

It goes without saying that the Power Pharmacist is an active member of his or her local and state pharmacy association, and coordinates outreach activities with them.

Thus equipped, the Power Pharmacist converts multiple patient dependencies into political and economic dependencies—using the pharmacy as a communication pipeline into the community for such outreach enterprises as voter registration, cholesterol screening and waste recycling. By linking these good causes to local politicians as patrons, the pharmacy intensifies its vitality and necessity.

Unlike other pharmacists, thousands of Power Pharmacists around the country are retrieving direct control of their businesses by making their pharmacies the hub of such relationships between constituencies that need and offer each other help.

With interlocking dependencies, the Power Pharmacist is thus automatically better able to refuse third-party contracts and deal directly with patients using trust-based 30-day credit and usual-and-customary pricing.

The Power Pharmacist has lifted his or her practice above the mere transfer of commodities to the exchange of resources, physical and intellectual.

By extending this power through other pharmacies, the Power Pharmacist signals his or her recognition of the fact that other pharmacies are only secondarily competition—primarily, they are additional points of power in a network of like practices.

Thus, when a local employer contemplates a cost-containing health benefits package that includes mandatory mail-order for maintenance medications, the Power Pharmacist is able to exercise a pincer-like counterattack.

On one side, the Power Pharmacist has the network-reinforced argument directly with dependent patients that the employer's plan will jeopardize a community health necessity.

On the other side, the Power Pharmacist's network can use political, civic and business leverage directly on the employer to preserve local assets—namely pharmacy jobs represented in the Power Pharmacist's store and network, and the communications links that serve such good (essential) causes as voter registration, cholesterol screening and waste recycling.

Because most employers are sensitive to their own business networks, they will think long and hard before adopting cost-cutting strategies that will disrupt them.

The main reason that local employers continue to adopt mail-order drug programs and plans that confine employees to in-house HMO pharmacies is that nobody has adequately pointed out the likely consequences to them.

In other words, those employers have not dealt with Power Pharmacists.

Why aren't there more Power Pharmacists? Like other people, most pharmacists don't like change; they know something needs to be done, but day-to-day survival comes first.

Unless the pharmacy is suddenly confronted with the catastrophic loss of a large block of patients, the gentle erosion of one or two patients at a time to mail-order isn't enough to catalyze the owner into action.

Little by little, almost without noticing, the ordinary pharmacist loses ground, while the Power Pharmacist gains it. It has been going on for centuries, in all fields of human endeavor.

My kingdom for a horse, said the king, as the enemy finally overwhelmed him.

This feature is written and presented by Jim Dickinson, on a grant from "Dickinson's Pharmacy – The Independent Voice., a professionally stimulating, practical 8–page monthly newsletter, available for an annual subscription fee of $45.00 from

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COLD FACTS ABOUT ACCIDENTAL HYPOTHERMIA (FROM THE NATIONAL INSTITUTE ON AGING)

Each year hundreds of older people die from exposure to the cold without ever leaving home.

Accidental hypothermia—a below-normal body temperature (typically 95°F or less) that can be life-threatening—may happen to anyone who is exposed to severe cold without enough protection. Older people are particularly vulnerable to the condition, according to experts at the National Institute on Aging (NIA). This is because as the body ages, its ability to endure long periods of exposure to cold or heat is lowered. Older people are frequently less active and may generate less body heat. As a result, they can develop accidental hypothermia even after exposure to relatively mild cold weather or a small drop in temperature.

There are a number of risk factors that can lead to accidental hypothermia. In addition to age, for example, the inadequate insulation in poor housing can lead to this condition. While many people believe alcohol makes them warmer, it actually causes a loss of body heat by dilating the blood vessels in the skin. Illness and certain medicines can also cause a decrease in body temperature.

To check for hypothermia, take the person's temperature. A temperature below 96°F will not register on an oral thermometer, which is a good sign that the person should be taken to a hospital. Other warning signs of the condition include a slow, irregular heartbeat, slurred speech, very slow breathing, and sluggishness and confusion. Any of these symptoms warrant emergency medical treatment.

Accidental hypothermia can be fatal if not detected and treated promptly. Treatment involves rewarming the person, preferably in a hospital under a doctor's supervision. Until then, the person should be kept wrapped in a blanket to stay warm and dry. Chances for a complete recovery are best when the person's body temperature has not dropped below 90°F and they are otherwise in good health.

How can you reduce your chances of getting accidental hypothermia? The NIA offers the following guidelines:

- Recognize if you are at risk and take precautions to keep warm , even in a mildly cold climate.
- Dress warmly in layers of clothing whether you're indoors or outside.
- Wear a hat, gloves, and other cold weather gear.
- Stay warm in bed by wearing enough clothing and using blankets.
- Keep active.
- Eat a balanced diet.
- Remember that body temperature can fall from drinking alcohol, being sick, or taking medicines.
- Ask a friend or neighbor to look in on you periodically during a cold spell. Or see if your community has a telephone check-in or personal visiting service for older people or the homebound.

Setting the thermostat in your home at 68°F in living or sleeping areas should be adequate. According to the NIA, there is no scientific basis for recommending specific room temperatures for older people, although people who are sick may need more heat.

For the free *Age Page: Heat, Cold, and Being Old*, send a postcard to the NIA Information Center/HCB, P.O. Box 8057, Gaithersburg, Maryland 20898-8057. ●

NEGOTIATION: CONFLICT AND COOPERATION

This is the twenty-third in a series of articles for professionals who manage and managers who lead professionals, and those who are both. Pharmacists operate with one license, but fill many different roles in hospitals, chain stores, individually-owned stores, industry, and educational settings. Along the way, they need a variety of management skills. These articles take a broad perspective on management concepts we hope you will be comfortable applying.

Dr. Curtis P. McLaughlin

A prior article in this series (Oct. 1991) discussed the process of negotiation within an ongoing relationship, emphasizing cooperation over competition. The cooperative mode of negotiation emphasizes:

Preparation; Having clear, general goals; developing effective alternatives rather than fixed positions.

Problem definition; Accurately representing underlying needs rather than holding all cards close to the chest.

Exploration; Full disclosure of the facts rather than hiding position or weaknesses.

Bargaining; Sticking to the major issues and keeping all options open rather than trying to trade points of little value for what you really value.

Closure; Working for mutual advantage and using a "nothing is ever final until all issues are settled" approach rather than taking issues off the table as soon as you get what you want.[1]

Most importantly, you need to know exactly what you and your organization really need and want, if you are to leave the table smiling. There is, however, no assurance, even with the best of intentions, that there will not be conflict during the negotiation process. If the parties were in complete agreement, we would probably not call the process a negotiation.

Gill suggests that negotiation in the health care environment is seldom a simple process. Virtually every negotiation is a complex one with multiple groups involved, usually some combination of payer, patient, provider and public interests. Just about every individual at the table *represents* not just themselves and their employing organization, but some other group with its own fragile consensus to be maintained. She notes that conflicts, or at least inconsistent positions, can be generated through:

A. *Constituency bargaining*: This is the typical situation in health care in which those who are at the table see themselves as representatives of some group, such as the nursing staff or the pharmacy technicians. They feel authorized to act only within the constraints of what they perceive will hold together a consensus among the group they represent.

B. *Horizontal bargaining*: The individuals on one side of the table have diffuse authority, or even authority conflicts among themselves. Those with formal authority still need the backing of the informal power structure. This is often the position of a group from the pharmacy in which the chief pharmacist must maintain the support of her professional associates.

C. *Unilateral bargaining*: This involves overt agreement between parts of the team on each side of the table without the agreement of their other team members. This may be an attempt to divide and conquer by the other side. More often it is due to a common professional point–of–view shared by individuals on both sides, but not by others on the negotiating team.

D. *Multilateral bargaining*: Here more than two groups are being represented in the process. State regulators may be meeting with a pharmacy delegation which is, in fact, three groups— independent pharmacists, chain store pharmacists, and hospital pharmacists.[2]

These situational or organizational conflicts involving authority are not the only sources of conflict—there may be conflicts based on the resources available or because of personal expectations. Gill suggests that many conflicts can come about because of differing personal perceptions (usually unspoken assumptions) about how people ought to behave (norms), differences in attitudes, and differences in values among the negotiators. To deal with these conflicts over norms, attitudes and values, Fisher and Ury suggest that the negotiator should be "hard on the problem and soft on the people."[3] What they are implying is that no matter how unprofessionally the opposition behaves, that is their problem and not yours. If their egos are threatened by the situation, you don't want to make it worse by counterattacking. Take responsibility for your own feelings and use "I" statements, instead of talking about "You." Listen actively and restate what you hear in objective, dispassionate terms. If you are angry, say so, but you don't need to act it out. If tempers really flare, it makes sense to adjourn or at least declare a recess.

In today's health environment the scarcity of resources is a common cause of conflict. Very frequently, the two sides are trying to divide up a pie that is shrinking. What do you do then? You have to turn the issue into a mutual problem. There is little hope of a win-win outcome if there is not enough to meet expectations. Braverman suggests that you use brainstorming techniques to get away from the zero-sum game mentality of if X wins, I lose.[4] Try working together to increase the mutually available resources instead of arguing about how to divide up existing ones.

During times of reduced resources be especially careful about the problem of representational bargaining. Where medical schools have faced reduced appropriations, they have often had to abandon dependence on the departmental chairs as an allocative body. The chairs are powerful, but they are first among colleagues and have to represent their colleagues' interests strongly and publicly. They have to defend their professional groups. To deal with that roadblock to negotiation, many organizations have had to set up a special negotiating committee of individuals who are highly respected but are not constrained by strongly representing a group. If they use rational, objective criteria, their deliberations can be accepted, not necessarily happily, by the various professional groups.

Conflicts on Your Side

When you are negotiating and things are not going well, do not assume that the other side is mean or irrational; try to analyze the situation in terms of the bargaining conflicts that might be causing problems. Analyze what the various agendas are on the other side and take them into account. Make sure that your side is consistent in its agenda and can act in concert. Be sensitive when the coalition on your side of the table might begin to unravel. Call an adjournment when you sense that is happening. If you are divided, let the other side know it, so that they can take that fact into account. That is the only way that they can make sense of your position and respond creatively to it.

The Abusive Negotiator

All of the good will in the world may not sway the abusive bargainer, the one who is bent on domination or on winning at any cost. What do you do about that situation? If you find that is your counterpart, bail out as soon as you can. To the extent possible, find other people to deal with. If you have to deal with such a person, if they have the power, do what is necessary to protect your integrity. Do not hesitate to state what you feel and what you see going on. Keep reminding yourself that the problem is with them, not with you. Sometimes they stop doing it when they realize that they can't hook you. I remember working for a professor in graduate school who loudly berated all who worked for him. He was an experienced editor and I learned a lot from him, but I stopped reacting to his tirades. One day he said "Curt, you're not reacting." I said, "No, Jim, it doesn't bother me, I know that you act that way with everybody." After that he stopped it. It didn't pay off for him any more.

Say what you think is fair at least once. You may not get it, but you have made your opinion known. If it is not accepted, don't take it personally. Keep referring to your BATNA (Best Alternative To No Agreement) and, if it isn't likely to materialize, cut off the bargaining and cut your losses. That way you are no worse off than if you didn't bargain, and you maintain your self-respect. Make your arguments with the same rationality that you would use in mutually beneficial bargaining situations. However, you may not choose to be completely open, since what you say may be used against you. Do not invest a lot of psychic energy in negotiations where the other party is just out to beat you down. Only play the game the way you believe it should be played. Life is too short for anything else.

[1] D. Greenberger, et. al., "Perception, Motivation and Negotiation" in S. M. Shortell and A. D. Kaluzny, Health Care Management: A Text in Organization Theory and Behavior, 2nd Ed., New York: Wiley, 1988, p. 134.

[2] S. L. Gill, "Elements of Conflict and Negotiation," Clinical Laboratory Management Review, July -August, 1987, pp. 187 - 194.

[3] R. Fisher and W. Ury, Getting to Yes: Negotiating Agreements Without Giving In, New York: Penguin Press, 1981.

[4] M. H. Brayerman, "Why Negotiations Go Wrong," Psychology Today, June 1986, pp. 54 - 58.

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CORRESPONDENCE COURSE

COUNSELING CONSUMERS ON OTC ENTERAL NUTRITION PRODUCTS

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Goals

The goals of this lesson are to:

1. discuss the rationale for enteral nutrition, and describe OTC enteral nutrition products;
2. categorize these products by use, and describe their actions, limitations, and overall utility; and
3. present important information to communicate to consumers to insure correct use of OTC enteral nutrition products.

Objectives

At the conclusion of this lesson, participants should be able to:

1. select the major food groups for supplying energy to the body, and describe the contributions and relative importance of each;
2. exhibit knowledge on OTC enteral nutrition products, citing their uses and misuses, limitations, precautions, and formulation considerations;
3. demonstrate an understanding of important advice to convey to consumers about correct use of OTC enteral nutrition products.

Many Americans agree that eating right is essential to good health and plan nutritious meals. Enteral nutrition and OTC products to provide it are not as well understood by consumers or pharmacists, even though the same principles apply.

This article discusses enteral nutrition and OTC products in this market. It differentiates between the various products and reviews how to assist consumers in selecting appropriate ones. It provides specific guidelines to follow when counseling consumers to assure compliance and reduce the chance for adverse effects. It also presents points for pharmacists' consideration, to effectively market the products and maximize their opportunity for repeated sales.

Background

Although food is required to sustain life, some individuals may not be able to eat well because of physical or mental impairment, lack of knowledge on good nutrition, or emotional or other considerations to consume sufficient food to assure adequate caloric intake. Or, they may eat an abundance of calories, but still consume a nutritionally-imbalanced diet.

A wide variety of enteral nutrition products are available over-the-counter to ensure that adequate nutrition is met. These products, along with associated supplies, represent one of the most vibrant segments of pharmacy practice. Annual sales are projected to approximate $900 million in 1990. It is possible that increases in sales will be substantially higher in future years, since Americans are living longer and taking better care of themselves. This will necessitate even greater demand for these products.

While they may seem complicated at first inspection, enteral nutrition products are not difficult to understand. Their ingredients, formulation considerations, and indications are based on sound principles of nutrition.

The Need for Balanced Nutrition

The human body requires nutrition to supply it with energy to operate. Energy is derived from calories provided by the three main food groups: carbohydrate, fat, and protein.

Carbohydrate is the most important energy source for humans. Excessive carbohydrate that is not needed immediately can be stored in muscle and liver as glycogen for later use. Stored glycogen will normally support energy needs for approximately half a day. After stores are depleted, the body will use fat, then protein, for energy.

Certain tissues, including the brain, blood cells, and kidney, require glucose exclusively for their energy requirements, even when carbohydrate intake is restricted and glycogen stores are depleted. Carbohydrate is readily converted into fat; the reverse reaction is limited. Less than 10 to 15 percent of glucose will be formed from fat during periods of early starvation.

Protein supplies most glucose in carbohydrate-starved persons. Protein is catabolized and then, through gluconeogenesis (i.e., formation of glucose from noncarbohydrate sources), reassembled in the liver to carbohydrate.

Table 1

Representative Enteral Nutrition Products

Product (Manufacturer)	Form
Amin-Aid (McGaw)	Powder, Pudding
Citrotein (Sandoz)	Powder
Compleat Regular Formula (Sandoz)	Liquid
Compleat Modified Formula (Sandoz)	Liquid
Criticare HN (Mead Johnson)	Liquid
Enrich (Ross)	Liquid
Ensure (Ross)	Liquid, Powder
Ensure HN (Ross)	Liquid
Ensure Plus (Ross)	Liquid
Ensure Plus HN (Ross)	Liquid
Entri-Pak with Entrition (Biosearch)	Liquid
Exceed (Ross)	Liquid, Powder
Forta Pudding (Ross)	Pudding
Glucerna (Ross)	Liquid
Hepatic-Aid (McGaw)	Powder, Pudding
Isocal (Mead Johnson)	Liquid
Isocal HCN (Mead Johnson)	Liquid
Isotein HN (Sandoz)	Powder
Lonalac (Mead Johnson)	Powder
Magnacal (Biosearch)	Liquid
Meritene (Sandoz)	Liquid, Powder
Nutri-Aid (McGaw)	Liquid
Osmolite (Ross)	Liquid
Osmolite HN (Ross)	Liquid
Polycose (Ross)	Liquid, Powder
Precision (Sandoz)	Liquid, Powder
Precision High Nitrogen (Sandoz)	Powder
Precision LR (Sandoz)	Powder
Portagen (Mead Johnson)	Powder
ProMod (Ross)	Powder
Pulmocare (Ross)	Liquid
Renu (Biosearch)	Liquid
Resource Instant Crystals (Sandoz)	Crystals
Ross SLD (Ross)	Powder
Stresstein (Sandoz)	Powder
Sustacal HC (Mead Johnson)	Liquid, Powder, Pudding
Sustagen (Mead Johnson)	Powder
Traumacal (Mead Johnson)	Liquid
Traum-Aid HBC (McGaw)	Powder
Travasorb (Travenol)	Liquid
Travasorb Hepatic (Travenol)	Powder
Travasorb MCT (Travenol)	Liquid
Travasorb Renal (Travenol)	Powder
Travasorb STD (Travenol)	Powder
TwoCal HN (Ross)	Liquid
Vital High Nitrogen (Ross)	Powder
Vitaneed (Biosearch)	Liquid
Vivonex, Standard (Norwich Eaton)	Powder
Vivonex, High Nitrogen (Norwich Eaton)	Powder
Vivonex T.E.N. (Norwich Eaton)	Powder

Unlike carbohydrate and fat, the body does not store excess protein. So when protein is catabolized to supply energy, various bodily functions including enzymatic reactions, muscular movement, and organ activity may be adversely affected. Loss of as little as one-third of the body's total protein can be fatal.

Healthy adults require 1,600 to 3,000 Calories per day. Actual requirement depends on the amount of physical activity, age and sex. A serious disease, or other stress, may increase the demand for additional calories. Dietary studies have shown that the distribution of calories in the average American diet is carbohydrate, 46 percent; fat, 42 percent, and protein, 12 percent.

Enteral Nutrition

Enteral nutrition is defined as the supplying of nourishment directly into the stomach. Such feeding is not new, having been described by early Egyptians and others. Primitive enteral nutrient feeding often involved gavage with milk, wine, broth, or other liquids directly into the rectum.

By the late-17th century, oral and nasogastric feeding tubes were used to deliver liquid nourishment directly into the stomach. Liquid flowed by gravity, or by pressure exerted upon it. The broth was commonly pureed meat, vegetables, fruit, eggs, fats, and oils. Or, it consisted of food products supplemented with sugars, cream, and dried milk solids. There was little or no attention given to assuring a balanced intake of essential nutrients.

Modern enteral nutrition products (Table 1) were first developed in the late-1960's and led the way to total home nutrition support. Before its development, persons with poorly functioning digestive tracts, or following surgery, were dependant upon parenteral administration of nutrients. They received dilute solutions of glucose and amino acids through a peripheral vein, or more concentrated solutions directly into the subclavian vein (hyperalimentation). Either way, they were dependant on parenteral hookups for their nutrition needs.

With enteral product development, individuals could receive all of the balanced constituents of a normal diet—carbohydrate, protein, and fat, and vitamins and minerals—through feeding per os (i.e., by mouth) when they can swallow, or via tube if they cannot swallow or have other gastrointestinal abnormalities. In fact, today, enteral feeding is preferred, whenever possible, over parenteral feeding. It is effective, less expensive, noninvasive, and associated with low potential for serious complications. Parenteral feeding is appropriate for short-tern use in a hospital or institutional setting, or when the GI tract is unable to absorb nutrients.

Enteral nutrition products are powder, crystal, or liquid formulations. Solids must be mixed with water or milk before consuming. Some liquids need diluting; others are ready to use.

Some formulae are intended to be used as dietary adjuncts to a normal, well balanced diet. They are not nutritionally complete, and should not be used as a sole source of nutrition. Other products contain balanced formulations of all required nutritional substances. These can sustain life for as long as would be expected from a well-balanced diet of traditional food.

Enteral nutrition products vary in proportion of carbohydrate, fat, protein, and fiber. They also differ significantly in taste, consumer acceptability, and cost.

Product selection is based on four criteria: caloric needs, other special requirements (e.g., lactose-free diet), palatability, and physician or dietitian recommendations. Many products deliver approximately 1 Calorie/mL. An intake of 1,500 to 2,000 mL of product each day, therefore, can supply 100 percent or more of the Recommended Daily Allowances, depending on the needs of the particular individual.

Product Administration

Enteral nutrition products can be taken orally, or administered through a tube. They can also be given via esophagostomy, jejunostomy, or gastrostomy routes directly into the stomach, duodenum, or proximal jejunum. Most products, especially those that are isotonic, are suited for administration through a feeding tube. They are also less likely to cause diarrhea, a common outcome of highly concentrated formulations.

Total enteral nutrition (TEN) is the equivalent of total parenteral nutrition (TPN), except that with TEN, nutrients are delivered by tube directly into the stomach. TEN is used when a person has a gastrointestinal affliction that precludes administration of nutrients by the oral route. An inability to swallow (dysphagia) is such an example.

Caloric Requirements and Enteral Nutrition Product Selection

People can be categorized according to their caloric need to maintain an ideal body weight. Daily requirements are based on broad groups, shown below. Reference body weight can be obtained from standard tables, or calculated thusly:

Men: 110 pounds for first 5 feet, plus 5 pounds for each inch over 5 feet.

Women: 100 pounds for first 5 feet, plus 5 pounds for each inch over 5 feet.

(1) Less than 2,000 Calories with increased protein. This requirement may be suited to elderly or bedfast persons who are physically inactive. It is also recommended for post-surgery patients, and others with infection or fractured bones. These individuals require fewer total calories, while maintaining a need for all normal nutrients, especially protein. Appropriate products which are low in residue include Ensure HR, Sustacal, and Precision HN; or Osmolite, which is low in residue, and also isotonic.

(2) From 2,000 to 3,000 Calories. Most individuals fit into this category, including persons with loss of appetite or cancer. Appropriated products for this group include Meritene, and Carnation Instant Breakfast; Ensure, Resource, and Travasorb, which are low-residue; Osmolite and Isocal, which are low-residue and isotonic; and Enrich, a high fiber product.

(3) More than 3,000 Calories. Persons with severe protein loss who have high caloric requirements include those with serious burns, sepsis, or multiple trauma. They require excessive calories to assist in complete healing. Enteral products that concentrate 1.5 to 2.0 Calories in each milliliter may be recommended. They are also appropriate for persons with anorexia, or cardiac or renal disease, who are on fluid-restricted diets. These products are generally not appropriate as sole nutritional therapy for routine use because of the chance they will cause dehydration. concentrated products that supply 1.5 Calories/mL include Ensure Plus (normal protein), and Ensure Plus HN, Isotein HN, and TraumaCal, which supply elevated protein; and Isocal HCN, Magnacal, and TwoCal HN, which supply 2.0 Calories/mL and elevated protein.

There may also be special patient needs that require individualization of enteral nutrition therapy. Specific product formulations can be selected to reflect these requirements.

Clear liquid diets (e.g., Citrotein, Ross SLD) are used prior to or after surgery, to provide all needed nutrients and help cleanse the bowel.

Isotonic products (e.g., Osmolite, Isocal) are indicated mainly for tubefeeding where gastrointestinal intolerance for food is of concern.

Low protein formulae (e.g., Amin-Aid and Travasorb Renal, Hepatic-Aid or Travasorb Hepatic) are for persons with renal or liver disorders respectively.

Low carbohydrate products (e.g., Glucerna, Pulmocare) limit carbon dioxide production, so have little respiratory depressant action. Persons with respiratory insufficiency or problems with CO_2 retention, or diabetes mellitus, may benefit from these products.

High carbohydrate polymers (e.g., Exceed) are used to supplement a traditional diet, rather that substitute for one. They are tasteless, and may be used by athletes and others to add carbohydrate and calories.

Nutrient-dense products are similar to other formulations but yield 1.5 to 2.0 Calories/mL. They are used by persons who have unusually high nutrient needs, or others with hepatic or renal disease who cannot tolerate large volumes of liquid.

Modular products (e.g., Moducal, Polycose, and Sumacal, carbohydrate; MCT and

Microlipic, fat; and Casec, Promix, and Promod, protein) can be combined as needed, or added to regular food, to provide specific dietary requirements of carbohydrate, fat, or protein.

Predigested or hydrolyzed formulae (e.g., Criticare HN, Travasorb HN, Vital HN) are partially digested proteins. They have been prepared by treating protein with acid or enzymes which hydrolyze them to di- and tripeptides. Persons with damaged intestines or limited absorptive surfaces, or pancreatic insufficiency, may benefit from these products. They are easily absorbed, and have less chance for causing diarrhea. Their taste may not be as palatable as nonhydrolyzed products.

Puddings (e.g., Forta Pudding, Sustacal Pudding) are semisolid products. They may benefit individuals with swallowing disorders who have difficulty consuming liquid formulations.

Pharmacists' Opportunities

The future market for enteral nutrition products will continue to grow. Pharmacists' opportunities will also continue to increase, paralleling the rapid growth in use of these products. Reasons for this upward trend include:

(1) government cost-containing programs for reimbursement of hospital costs promoting home, rather than institutionalized, care; (2) an aging population assuring an even greater number of product users in the future; and (3) advances in technology making enteral nutrition products more reliable, easy to use, and better tasting and tolerated.

Individuals requiring enteral nutrition products will welcome a complete pharmacy inventory of products representing a full variety of flavors, attractively merchandised, possible in a separate department within the pharmacy near other home health care products. Enteral nutrition products are currently displayed haphazardly in many pharmacies' weight control, or "health-food" sections. Such placement may have been acceptable in the past, but times are changing! Enteral nutrition products are neither diet beverages nor health food supplements. They are not fad items. Rather, they are highly professional, balanced nutrition replacement products.

Product manufacturers can be contacted and

Table 2

Risk Factors for Poor Nutritional Status

Dietary History

Anorexia; poor food intake
Alcohol abuse
Chewing or swallowing difficulties
Fad or restricted diets
Frequent skipping of meals
Lack of nutrient intake for 10 or more days

Drug Administration

Antibiotics
Anticonvulsants
Antineoplastic agents
Oral contraceptives

Medical History

Cancer
Circulatory disease
Chronic disease of GI tract, lung, liver, or kidney
Coronary artery disease
Depression
Diabetes mellitus
Heart failure
Hyperlipidemia
Mental retardation
Nausea and vomiting, diarrhea
Neurologic disorders
Pancreatic insufficiency
Paralysis
Surgery involving GI tract
Recent surgery or illness

Socioeconomic History

Elderly, solitary living and eating habits
Handicap or other infirmities
Inadequate food budget
Inadequate food-preparation or storage

asked to supply educational and marketing information about their products. This information can be used for self-education, and distribution to patients.

Pharmacists may contact users of enteral nutrition products, physicians, dietitians, and nursing home administrators personally, and reinforce these contacts through advertising. Willingness to provide a broad assortment of products and auxiliary equipment, desire to assist in product selection, and offer to advise and counsel on nutritional needs, should be emphasized. Manufacturers may also have specific information for pharmacists to use when detailing health care providers.

A professional development program made possible by an educational grant from

SEARLE

Counseling Consumers on Enteral Nutrition Products

Pharmacists, by supplying enteral nutrition products, should be alert for signs of malnutrition in persons purchasing them. Visible manifestations of nutrient deficiency include mouth fissures and gum disease, skin breakdown, or weight loss exceeding 10 percent of normal body weight. Such persons should be counseled to seek professional intervention as soon as possible. Conditions predisposing to malnutrition include those listed in Table 2.

If the reason for self-determined supplementing calories or protein in an otherwise healthy person is to assure a balanced nutritional intake, a complete formula product should be recommended. If the reason is to assist the person gain weight after recently experiencing an unexplained weight loss, the individual should be referred to a physician. Such loss may represent serious pathology that requires professional intervention.

Consumers can select from a variety of products that are indicated for similar use, in order to satisfy personal taste considerations. Products such as Vari-Flavors consist of flavor packs that can be added to other enteral formulations to help prevent flavor fatigue. Product manufacturers can also be asked to supply recipes that use enteral nutrition products to create a variety of tasty dishes. These may help reduce the monotony of repeated consumption of single-flavored, or similar-consistency, products. The products generally taste better when cooled. Unopened containers can be stored at room temperature. Unless otherwise instructed, the products are sipped in amounts of 3 to 5 ounces at a time.

Users should carefully wash their hands before opening a container. Container tops should be washed with water and wiped dry before opening. Enteral nutrition products are sterile until opened, but are excellent media for microbial growth once the seal is broken. When opened, the unused portion of product should be kept refrigerated and used within 24 hours (or longer if so specified on the label).

Those who provide care to patients who receive nutrition through a feeding tube should be instructed on proper maintenance of the equipment. Unless instructed otherwise, a nasogastric tube should be rinsed with water 3 times a day. A pump, if used, should be checked regularly to assure accurate delivery.

There is a support group that emphasizes personal contact with other people on enteral nutrition. Interested persons can be instructed to contact: The Oley Foundation, 214 Hun Memorial, Albany Medical Center, Albany NY 12208. •

CORRESPONDENCE COURSE QUIZ

OTC Enteral Nutrition Products

1. The body stores excess supplies of all of the following EXCEPT:
a. carbohydrates.
b. fat.
c. protein.
d. vitamins/minerals.

2. According to information in the article, the most important difference between TEN and TPN is:
a. TEN is administered intravenously; TPN is given orally.
b. TEN is used for patients with dysphagia.
c. TEN is much more effective than TPN.
d. TPN delivers nutrients by means of a tube to the stomach.

3. All of the following are "modular" products that contain high amounts of either carbohydrate, fat, or protein and are used to provide specific dietary requirements EXCEPT:
a. Moducal.
b. Casec.
c. MCT.
d. Pulmocare.

4. The most important energy source for humans is:
a. carbohydrates.
b. fat.
c. protein.
d. vitamins/minerals.

5. The storage component in the body that serves as a large reservoir for the energy source referred to in question #4 above is:
a. adipose tissue.
b. glycogen.
c. gallbladder.
d. steroids.

6. A request for a predigested or hydrolyzed formula should be filled by dispensing:
a. Isotein HN.
b. Ensure Plus.
c. Osmolite HN.
d. Criticare HN.

7. All of the following points are important to pass along to persons purchasing enteral nutrition products EXCEPT:
a. they are sterile until opened.
b. they are excellent media for microbials.
c. they should be kept at room temperature and discarded 96 hours after opening.

8. Which of the following is a product that could be suggested on request for an enteral supplement that has low residue and is isotonic?
a. Glucerna
b. Glucola
c. Isocal
d. Isolyte

9. All of the following tissues require glucose exclusively for their energy source EXCEPT:
a. blood cells.
b. kidney.
c. brain.
d. liver.

10. Which of the following is commercially available in liquid, powder, and pudding dosage forms?
a. Compleat
b. Exceed
c. Precision
d. Sustacal

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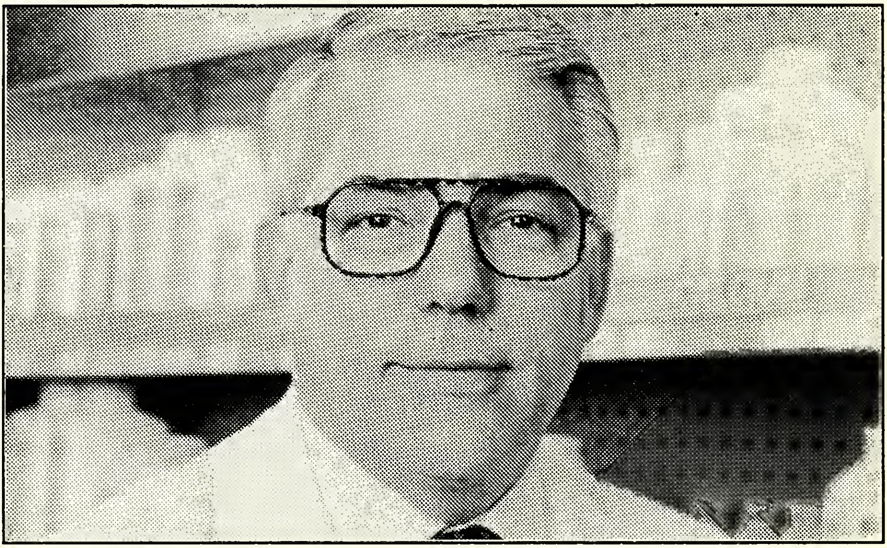

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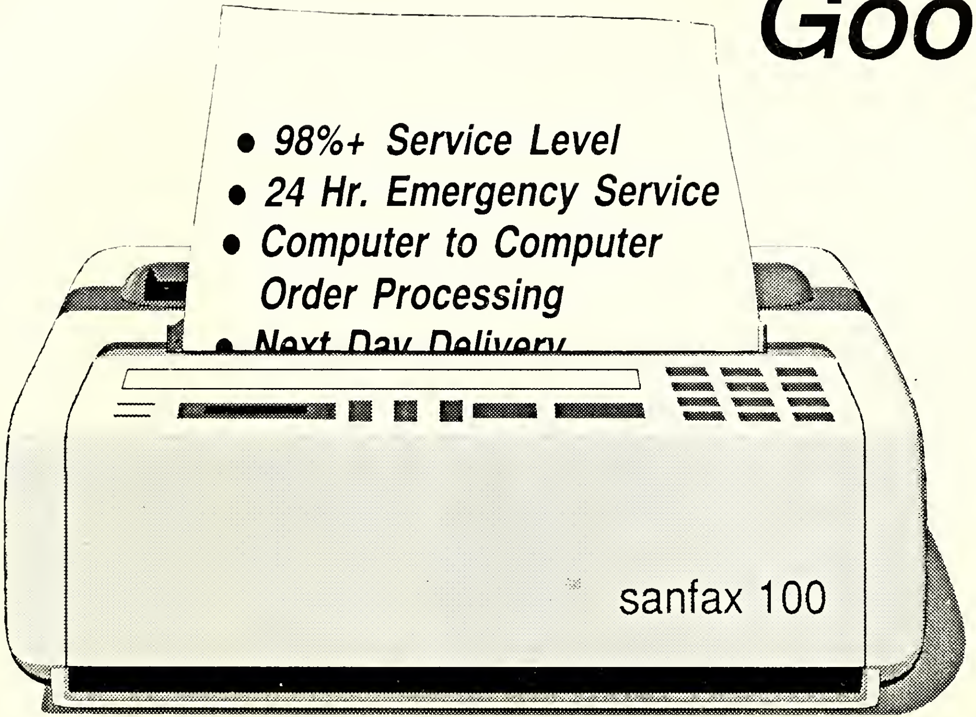
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Important figures in diabetes care

7

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1

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[1] *Diabetes Surveillance, 1980-1987.* Atlanta, Ga. US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.

[2] *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

SCHERING REPORT 14
PHARMACISTS' ROLE IN IMPROVING PATIENT MEDICATION COMPLIANCE

Patients are failing to take their medications as prescribed at an alarming rate, with serious consequences to patients, physicians, pharmacists and the nation's rapidly escalating health care costs, according to a new, independent survey commissioned by Schering Laboratories.

"If people don't take their prescribed medicines properly, they are less likely to get better," said Dr. Jack Robbins, Director of Pharmacy Affairs, Schering Laboratories. "In the long run, these patients will require greater amounts of health care—often including hospitalization—when simply taking their medications as directed would have led to a rapid recovery."

Schering Report 14, "Improving Patient Compliance: Is There a Pharmacist in the House?" explores the evidence and consequences for patients, physicians and pharmacists—the three groups directly involved—and suggests that patient compliance has not improved perceptibly since 1987, when Schering Report 9 first examined the problem. The study was based on interviews with 2,000 adults representing a demographic profile of the U.S. population.

"The nation's health care bill passed the three-quarters-of-a-trillion-dollar mark last year, and a large part of that cost comes from improper patient compliance," Robbins added. "This is not just a dollars-and-cents issue; we are talking about people who are involved—patients, physicians and pharmacists."

"Patients pay the toll in prolonged sickness, hospitalization, lost workdays, higher insurance costs and even death," he continued. "Doctors are baffled by the apparent ineffectiveness of treatment, and find that non-compliant patients are simply wasting their time and training. Pharmacists, because of poor patient compliance, fill and refill fewer prescriptions than they should, and they observe how their patients fail to benefit from the therapies prescribed for them."

In defining the issues, the survey noted three facets of improper patient compliance: when patients get a prescription from the doctor but do not have it filled; when patients do not take the medication as prescribed; when patients do not follow instructions and fail to have the prescription refilled.

Examining physicians' prescribing patterns, the Schering Report noted that eight of 10 adult Americans (79 percent) visited a doctor in the past 12 months. Women (86 percent) visited doctors more often than men (72 percent), and patients over age 55 (87 percent) visited doctors more often than those under 55 (77 percent).

Why are so many patients crowding doctors' waiting rooms? Most often, it is for a routine physical (40 percent), or to follow up on an existing condition (33 percent). One in five (21 percent) seek help on a "new problem," with younger patients most likely to cite a "new health problem."

But not every visit leads to a written prescription. "Barely half (52 percent) of physician visits resulted in a prescription," Robbins said. "Of patients who received a prescription, 39 percent of the time they received two or more."

The survey also asked patients who received prescriptions how much time the doctor spent counseling them about the medications. Some 88 percent reported that the doctor told them "how much to take or apply each time" and the same percentage recalled the doctor telling them "how often to take it." Somewhat fewer (81 percent) said they were told "how long to continue taking it."

How do these replies compare with results of the Schering Report five years ago? "The rate of medication advice by physicians fell for all three factors—from 92 percent to 88 percent for information on both dosage and frequency, and from 87 percent to 82 percent on how long to continue taking the medicine," Robbins reported.

Based on these data, the Schering Report suggested that doctors are even busier today, with less time for patient counseling. This means that the pharmacist's role in filling the counseling gap is even greater than ever.

"The economic consequences to pharmacists resulting from patients failing to fill their initial prescriptions— 8.7 percent of those interviewed—are startling," Robbins said. "Based on the approximately 1.6 billion prescriptions written each year—with an average retail value of $20—we're talking about a shortfall at the pharmacy counter of about 140 million prescriptions worth $2.8 billion.

"Dividing that figure equally into the nation's approximately 55,000 pharmacies means that each pharmacy is coming up short by about $51,000 per year, or about $1,000 per week, from potential patients who don't have their prescriptions filled," he added.

The Schering Report noted that the number of patients neglecting to fill their prescriptions could possibly be much higher than people admit. What is clear, however, is that more patients today are admitting that they are not bothering to fill their prescriptions than a short five years ago, when the figure was only 7 percent.

"Perhaps there may be a link in the drop in prescription-filling with the reported drop in the level of physician counseling," Robbins suggested.

What reasons did these people give for not filling their prescriptions? The reasons given most often were: "I didn't need the medicine because the condition improved or disappeared on its own…I still have enough of that medicine from a prior prescription…The doctor gave me some samples, and I'll fill the prescription after I have used up the samples."

When patients do have their prescriptions filled, are they loyal to their regular pharmacist? Four out of five (81 percent) say they "usually have (their) prescriptions filled at the same pharmacy all of the time."

The greatest opportunity for the pharmacist to counsel patients is when they personally visit the pharmacy to drop off—and especially to pick up— prescriptions, the Schering Report observed. Based on the people interviewed, seven out of 10 (69 percent) personally brought their most recent prescription to their pharmacy, and also picked it up.

"A patient picking up a prescription has the right to expect professional counseling about the proper way to take the medication, as well as possible side effects, interactions and anything else the patient should know about the medication prescribed," Robbins said. "Among those who picked up their prescriptions, only slightly more than half (52 percent), received the medication from the pharmacist, while 48 percent received it from a clerk."

The survey cited concern about the consistency with which pharmacists counsel patients on how and when to take medications. "The pharmacist's counseling is vital," the Schering Report pointed out, "because patients often become flustered in the doctor's office and forget or misremember any instructions the doctor may have given them."

The survey results show that counseling by pharmacists is also distressingly sparse. Only 25 percent of patients were told how often to take the medicine, with the same percentage being told how much to take or apply each time. Only 21 percent received instructions on how long to continue taking their medication.

Robbins observed: "Since the Schering Report of five years ago, the rate at which information is given to patients by pharmacists on frequency has fallen 15 percentage points, from 40 percent to 25 percent; on dosage by 18 percentage points, from 43 percent to 25 percent; and on duration by 15 percentage points, from 36 percent to 21 percent.

"If this is indicative of a trend," he added, "we can expect that in a few years pharmacists will wordlessly toss the medications over the counter to patients."

While the amount of information pharmacists are giving—or most often not giving—may be disappointing, their patients do not seem to mind at all. "Seventy-four percent of people interviewed said they were completely satisfied with the verbal and written instructions provided by their pharmacist," Robbins said.

The Schering Report noted that the physical setting of the pharmacy itself may discourage the interchange between pharmacist and patient - no privacy, too many people around, too much chance for embarrassment. "There might be more communication if separate consulting areas, now found in only a few pharmacies, became more common," it suggested.

Only 3 percent of the people interviewed reported that when they do speak to the pharmacist, the interchange takes place in a "separate location set aside for consulting." Fifty percent felt that a private consulting area in the pharmacy would be desirable, with women and younger patients the most fervent proponents.

While most patients appear to be satisfied with the amount of information provided by pharmacists, when, if ever, do patients think the pharmacists "should talk to them personally about their prescription?"

Twenty-seven percent of the patients said every time a prescription is filled. The remainder put the initiative either on the patient, with 36 percent saying only if the patient asks; or on the pharmacist, with 32 percent saying only when the pharmacist thinks it is necessary.

To find what value patients place on pharmacists' time, the survey asked, "How much should be added to the cost of the prescription as the pharmacist's consulting fee, if a law required pharmacists to consult with patients." The most popular answer was, as anticipated, "nothing" (64 percent), followed by "I don't know" (23 percent). Among patients who responded with a dollar amount, the average was $2.17, which, while a low figure, suggests that patients do place a value on the pharmacist's counseling role, Robbins said.

To gauge how patients feel about the pharmacist as a professional health care counselor, they were asked whether they agreed or disagreed with these statements:

- "The pharmacist's verbal instructions are very clear and complete." Almost two-thirds (63 percent) strongly agreed.
- "The pharmacist is usually busy, but will spend as much time with me as I need to discuss the prescription." Just over half (52 percent) strongly agreed.
- "The pharmacist answers questions I didn't think to ask the doctor." Only one in three (36 percent) agreed, and a significant 20 percent disagreed.

"If pharmacists are indeed ready to fill the breach in the doctor's instructions, they have not successfully demonstrated this to their patients," Robbins observed.

Cutting to the heart of the pharmacist-patient relationship, 45 percent of those interviewed strongly agreed that "the pharmacist really cares about me and how I feel."

The survey explored the possibility that patients feeling ill at ease or perhaps embarrassed at the checkout counter might discourage conversation. To the statement, "Sometimes I'm embarrassed to ask the pharmacist a question about the medicine," a mere 8 percent strongly agreed and 75 percent disagreed. "Understandably," the Schering Report commented, "younger patients are most likely to admit to embarrassment in view of their limited history of visiting pharmacies to fill prescriptions."

Following the patient noncompliance trail, the Schering Report tracked how well patients followed directions for taking medications. Eighty-one percent claimed they follow directions exactly, leaving 19 percent as admitted noncompliers.

The survey also revealed a significant difference in patient compliance, depending on who in the pharmacy handed the finished medication to the patient. When the pharmacist, rather than a clerk, handed the medicine to the patient, noncompliance was reduced by 25 percent.

What reasons did patients offer for not following directions? Leading the list were: "I forgot…I took different amounts…I took it at different times." Mentioned less frequently were: "I only took it when I needed it…I was too busy to take it…The side effects bothered me."

Focusing on patients who filled their prescription and took it either as directed or as they decided to on their own, did the medication help them? Ninety percent agreed that it did, 6 percent said it did not and 4 percent said they were not sure.

The Schering Report also cited an apparent link between taking the medication as directed and its effectiveness. Eighty-seven percent of patients who failed to take the proper dosage said the medication did not work. Sixty-six percent of patients who did not take medication at the proper times said it did not work, and 49 percent who neglected to take it for the full duration faulted the medication.

"When patients are not fully satisfied with counseling, they are much more likely to say the medication failed to do what it was supposed to," Robbins noted. "Overall, 6 percent of those interviewed said the medicine failed against 16 percent who were dissatisfied with the pharmacy's instructions and 18 percent who were dissatisfied with the doctor's counsel."

Examining the third facet of improper patient compliance—not having prescriptions refilled—the survey reported that two out of three patients (66 percent) recalled that their doctors told them whether or not the prescription should be refilled. But the number of patients who received advice on refills from their pharmacists fell to only 18 percent.

"What a missed opportunity to bring the patient back—when the patient should be brought back to the pharmacy," Robbins pointed out. "Pharmacists might help patients remember to refill prescriptions by reminding them at about the time the initial prescription runs out. But only one in 20 patients (5 percent) recalls getting such a reminder from their pharmacy."

Putting the findings into perspective, the survey reported that doctors got good scores on instructing patients on dosage, but slipped somewhat on possible side effects and interactions with other drugs or alcoholic beverages. Pharmacists most often failed to provide guidance to patients, and at an alarmingly higher rate than even five years ago.

Acknowledging that pharmacists are trained, dedicated and caring professionals who want to help patients get well—and that good patient compliance is good pharmacy business—the Schering Report proposed that pharmacists consider these steps to help improve patient compliance:

- Come out from behind the pharmacy counter and talk face-to-face with patients. Don't leave it to a clerk.
- Make sure the atmosphere is congenial. Set aside a separate counseling area.
- Don't be shy about the "personal" aspects of the patient's malady as they relate to the medication. Patients aren't shy.
- Keep in mind a mental checklist of the "basics"—dosage, frequency and duration, and add side effects and possible food and drink interactions.
- Alert patients to possible interactions with other medications by using the pharmacy's computer records on other drugs they might be taking.
- Provide written instructions on medications and tell patients you will be glad to answer any questions.
- Use brightly colored precaution labels on prescription containers.
- Display, near the register, items that remind people when to take medication: "counter caps" or medicinal bottles with digital alarms.
- Update patients' computer records after speaking to them.
- Offer to participate in "brown bag" screenings organized by senior citizen centers where participants bring all their medications to be reviewed.
- Develop a program to remind patients about prescription refills.

The Schering Report urged pharmacists not to lose sight of their professional responsibility to use these "tools" diligently and consistently. "Pharmacists must renew their commitment to help increase patient compliance and, thereby, in their own way, attack the nation's growing health care cost problem. It's not only good business, it's good medicine."

A booklet summarizing the Schering study is available by writing: Pharmacy Affairs Department, Schering Laboratories, Kenilworth, N.J., 07033.

Schering Laboratories is the U.S. prescription pharmaceutical arm of Schering-Plough Corporation, a research-based company engaged in the discovery, development, manufacturing and marketing of pharmaceutical and health care products worldwide.

CAPPING MEDICAID PRESCRIPTION DRUGS MAY BACKFIRE

One of every 5 states limits the number of prescription medicines Medicaid patients can purchase at public expense. But a new Harvard University study funded in part by the Agency for Health Care Policy and Research (AHCPR) suggests that capping policies may harm frail, elderly Medicaid enrollees and possibly cost states more in increased nursing home and hospital care than they save in reduced drug purchases.

In a previous analysis, also supported by AHCPR, the investigators found that prescriptions filled for heart disorders, diabetes, and other chronic diseases by New Hampshire Medicaid enrollees 60 years of age and older declined sharply after the state limited the number of drugs a beneficiary could receive under the program to three a month. New Hampshire later dropped the cap in favor of a $1 co-payment per drug, and utilization rates rose to close to what they had been before the cap was imposed.

The new analysis shows that the 3-prescription cap also was associated with a significant increase in nursing home admissions. During the 11 months that the cap was in effect, members of the New Hampshire study group were 1.8 times more likely to enter nursing homes than a group of similar patients in New Jersey—a state that did not limit drug purchases. The risk for the sickest patients in the group—those who regularly received three or more drugs a month prior to the cap policy—was even higher. These patients were 2.2 times more likely to enter a nursing home than their New Jersey counterparts. When the cap was replaced by the co-payment policy, the excess risk of admission to a nursing home ceased. In general, those patients who were admitted to nursing homes did not return to the community.

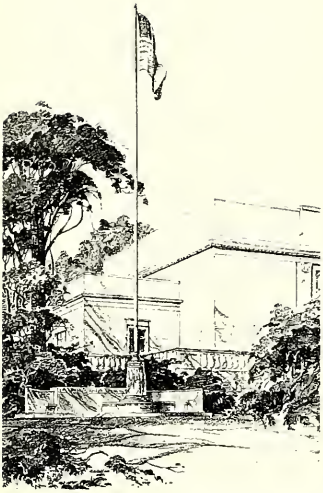
There also was a moderate trend toward increased hospital admissions during the cap period, but this increase was not statistically significant. The researchers did not have access to Medicare data, which would have allowed them to conduct time-series analyses of all hospital admissions.

According to the investigators led by Stephen B. Soumerai, Sc.D., the excess months of nursing home use associated with the capping policy cost New Hampshire at least $310,745. However, this figure underestimates the true cost since it does not include physician fees and certain other costs. If these additional expenses were included, the cost might have well extended the estimated $300,000 to $400,000 that the policy saved in statewide drug expenditures.

Since admission records were not available for this study, the researchers were unable to distinguish nursing home admissions due to declining health from admissions seeking to avoid the drug limit. Regardless of the mechanism, the authors believe the cap precipitated nursing home admissions.

AHCPR's Center for General Health Services Extramural Research funded the study under grant HSO5947.

Details are in "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes," by Dr. Soumerai, Dennis Ross-Degnan, Sc.D., Jerry Avorn, M.D., and others. The article was published in the October 10, 1991 issue of the *New England Journal of Medicine* 325 (15), pp. 1072-1077.



Help us honor Pharmacists who fought for our country!

WITH YOUR HELP, APhA WILL HONOR PHARMACISTS WHO SERVED IN THE MILITARY DURING THE KOREAN, VIETNAM, AND PERSIAN GULF CONFLICTS.

The recognition will consist of a sculptured bronze plaque to be added to the American Pharmaceutical Association Flagpole Memorial which is dedicated to all pharmacists who served in the U.S. military. Less than a block away are other famous Washington landmarks including the Lincoln Memorial and the Vietnam Memorial.

The flagpole, which was installed in 1948, rises from a marble and granite base with a sculptured bronze drum depicting six uniformed pharmacists from the Revolutionary War to World War II. The new sculpture, to be installed on the wall which forms the marble seat adjacent to the flagpole, will depict uniformed male and female pharmacists who served in the U.S. Army, Navy, and Air Force during the Korean, Vietnam, and Persian Gulf conflicts.

Pharmacists and members of their families, pharmacies, pharmaceutical associations, and the pharmaceutical industry are urged to support this memorial through contributions of $25.00 to $1,000.00 each. Contributors have the option of designating the name of a pharmacist who served in the Armed Forces whose name will be inscribed on a special scroll that will be on perpetual display at APhA headquarters. The names of all contributors will also be appropriately recognized.

With your help, the tribute honoring those pharmacists who served in Korea, Vietnam, and the Persian Gulf will be installed in ceremonies held at APhA headquarters sometime in 1992. Act today by completing and mailing this contribution form.

☑ I want to support efforts to honor pharmacists who fought for our country.

☐ I am attaching a check in the amount of $________ made payable to the "AIPEF" (American Institute of Pharmacy Endowment Fund).

☐ **Please inscribe the name(s) of the following pharmacist(s) who served our country.**

☐ **Please record my contribution as a tribute to *all* pharmacists who served our country.**

____

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Contributor Name ____________________________________

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AMERICANS WITH DISABILITIES ACT OF 1990 PART II: ACCESSIBILITY REQUIREMENTS

Denise Stanford Haskel
An associate with the Raleigh law firm of Bailey & Dixon

Under the Americans With Disabilities Act (ADA), places of public accommodation must ensure that their goods or services are accessible to the disabled. A pharmacy is considered a place of public accommodation under the ADA. To comply with the ADA, pharmacies must make reasonable modifications in their policies, practices, or procedures when these modifications are necessary to allow the disabled to utilize their goods, services, or facilities, unless the pharmacy can demonstrate that the modification would fundamentally alter the nature of the goods, services or facilities. For example, at least one accessible check-out aisle should be provided during store hours to allow persons with mobility impairments to make their purchases.

A pharmacy must provide auxiliary aids and services, if necessary to ensure that the disabled are not denied services, unless the pharmacy can demonstrate that providing particular auxiliary aids and services would fundamentally alter the nature of the goods, services or facilities, or would result in an undue burden. An undue burden is a provision that would be significantly difficult or expensive to implement. A pharmacy must provide an existing alternative auxiliary aid or service that would not be a fundamental alteration or burden. Examples of auxiliary aids and services include: written materials, taped text, audio recordings, Braille materials, large print materials, or other effective methods that would make aurally and visually delivered materials available to individuals with hearing and visual impairments. However, a pharmacy is not required to provide its customers with personal devices, individually prescribed devices, or services of a personal nature. In addition, a pharmacy must furnish appropriate auxiliary aids and services necessary to ensure effective communication with the disabled.

A pharmacy must remove architectural barriers in existing facilities, including structural communication barriers.

A pharmacy must remove architectural barriers in existing facilities, including structural communication barriers, where such removal can be accomplished easily and carried out without much difficulty or expense. Examples of barrier modification include, but are not limited to: installing ramps; making curb cuts on sidewalks and entrances; repositioning shelves; rearranging tables, chairs, vending machines, display racks, and other furniture; repositioning telephones; installing flashing alarm lights; widening doors and doorways; eliminating turnstiles or providing an alternative accessible path; or creating designated accessible parking spaces. If the pharmacy can demonstrate that barrier removal is not easily accomplishable and able to be carried out without much difficulty or expense, the pharmacy must make its goods, services or facilities available through alternative methods, if those methods are readily achievable.

All new construction after January 26, 1993, must be readily accessible to and usable by the disabled. Alterations to a structure after January 26, 1993, must be readily accessible to and usable by the disabled. Alterations to a structure after January 26, 1992, must be made to ensure that, to the maximum extent feasible, the altered portions of the facility are readily accessible to and usable by the disabled. All new construction and alterations must comply with the Accessibility Guidelines for Buildings and Facilities published by the U.S. Architectural and Transportation Barriers Compliance Board.

The Department of Justice has published rules regarding nondiscrimination on the basis of disability in public accommodations and commercial facilities. These rules became effective on January 26, 1992, with certain exceptions. All pharmacies and pharmacists should take prompt action to comply with ADA requirements. ●

DRUG STORE RULES IN 1854

"Store will be opened promptly at 6 a.m. and remain open until 9 p.m. the year 'round. Store must not be opened on the Sabbath day unless absolutely necessary and then only for a few minutes."

"Any employee who is in the habit of smoking Spanish cigars, getting shaved at a barber shop, going to dances and other places of amusement, will most surely give his employer reason to suspect his integrity and all around honesty."

"Each employee must attend Sunday School every Sunday. Men employees are given one evening a week for courting purposes and two if they go to prayer meeting regularly. After 14 hours of work in the store, the remaining leisure time must be spent in reading good literature."

Thanks to an Alamance County pharmacy for supplying this model work document.

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7. TABOR CITY MEDICINE MART
   Tabor City
8. NEIL'S PHARMACY
   Huntersville
9. BIRMINGHAM DRUG
   Hamlet
10. MEDICAL PARK PHARMACY
    Cary
11. BRYAN DRUG CO.
    Tarboro
12. DENTON PHARMACY
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***Roland Thomas**, Pharmacy Planning Specialist*
3555 Tryclan Drive, Charlotte, NC 28217

LETTERS OF INTEREST

Dear Mr. Mebane:

We have received a number of inquiries from pharmacists regarding The Dow Chemical Company's new prescription drug program for its U.S. associates. As a pharmacist, I can appreciate their concern about any intrusion of competitive force in the prescription business. When that competitive force has an uneven playing field advantage, we agree that there are even more reasons for concern and upset.

There are two very important points I would like for you to clearly understand:

1. The Dow Chemical Company also understands this and has changed its prescription drug plan, as you can see from the letter enclosed from Robert Baughman, vice president of Human Resources for Dow U.S.A., and the notice sent to all U.S. Dow employees titled, "Look for VALUE in Pharmacy Services."
2. Marion Merrell Dow is a separate, self-standing organization that has no control over what goes on at The Dow Chemical Company. I hope you will recall that Marion was the first company in our industry to provide prescription benefits to our associates, utilizing the usual and customary fee for pharmacists. That benefit was introduced in 1982. Today, as Marion Merrell Dow, we remain committed to that approach.

We hope you also will understand that we consider pharmacy to be a primary partner of ours in the delivery of quality medications to the patient population of the United States. If you will look back over the years, I think you will find that Marion and Merrell Dow, and now Marion Merrell Dow, have very effectively worked with pharmacy to continually reinforce the importance of this partnership.

If you have comments or suggestions that you think will help the way we at Marion Merrell Dow work with pharmacy, we'd be most pleased to receive your ideas.

Sincerely,
Fred W. Lyons, Jr.
President and Chief Executive Officer

The following letter was enclosed with that of Mr. Lyons and is a sample of what was sent to all U.S. Dow employees.

"Look for VALUE in Pharmacy Services"

Thank you for sharing your interest and concern in the new Dow U.S.A. Prescription Drug Plan. This Plan, part of our total "Choices" benefits program, is aptly named because it truly offers a wide range of choice for our employees and retirees.

Under the Prescription Drug Plan, employees and retirees may choose—each time they have a prescription filled—to use any one of three Plan options: Network Pharmacy, Non-Network Pharmacy, or a Mail Service Pharmacy for maintenance prescription drugs. There are no Plan mandates to use any particular one of the three options, and the employee co-pay is the same for Network and Mail.

As we have gained experience with the Plan, we have made some adjustments to achieve better balance. This has included removing a deductible amount from the Network Pharmacy option (making it identical to the Mail Order option), and making an upward adjustment in the dispensing fee paid to pharmacies. We have communicated extensively with our employees and retirees about the features of all three options, and also about the value-added services they should expect from local pharmacies.

The hard fact of life for Dow, and any company these days, is that we simply must contain our skyrocketing health care benefit costs. The Prescription Drug Plan is one of many efforts Dow has underway toward this goal. Frankly, Dow could have saved much more money with a more rigid plan. Of the many cost management options we have studied, this was among the least onerous for Dow people and for local pharmacists. You may also be interested that we personally invited all pharmacists in Dow locations to participate in the Plan. We very much understand the value that our pharmacist providers add to our Dow active and retiree family in drug therapy.

Our employees and retirees across the U.S.A. have been most supportive of the new Plan, and their enthusiasm is steadily growing as they work with it and experience first-hand its range of choices and cost-management options.

We must continue our search for ways to offer our employees and retirees cost-effective quality health care and at the same time balance the needs of Dow and Dow people with the needs of the providers of care.

Sincerely,
Robert M. Baughman
Vice President
Human Resources
Dow U.S.A.
The Dow Chemical Company
Midland, Michigan

CAMPBELL STUDENT SELECTED AS BRISTOL-MYERS SQUIBB SUMMER INTERN

Ms. Cindy Yuen, a fifth year Pharm.D. student at Campbell University School of Pharmacy, has been selected to participate in the 1992 Pharmaceutical Industry Summer Internship Program at the Bristol-Myers Squibb new facility in Plainsboro, New Jersey.

The program, coordinated through the National Pharmaceutical Council and the APhA Academy of Students of Pharmacy, runs from 1 June through 14 August, and provides students an industry background they can't get in a classroom. Students will be assigned to product teams. Ms. Yuen will work with metabolics and will attend seminars and complete special assignments during the summer.

THE PEOPLES' FORUM

Raleigh News and Observer

PHARMACEUTICAL SENSE

When state employees begin "price–shopping" for their prescription drugs because of new provisions in their insurance reimbursement, they should not overlook their neighborhood pharmacies in favor of large chains.

Not all independently owned pharmacies have higher drug costs, as comments in the March 26 article would lead one to believe. As an independent pharmacy owner competing with five other drugstores in my small town, I would be foolish indeed to charge outrageous prices knowing my customers can easily shop elsewhere. Every drugstore has items that are "loss–leaders." But across the board, all pharmacies operate on basically the same price margins.

And there is an issue the state health plan has overlooked—quality pharmacy care. Drug care needs to be monitored by a trained pharmacist who has a relationship with the patient and can deliver a continuum of care. When customers are forced to drive from pharmacy to pharmacy to get the lowest costs on one drug here and another drug there, their drug care is jeopardized.

A customer needs to develop a relationship at one pharmacy for the same reason he visits only one doctor: continuity, trust and common sense. But then, if common sense were important to the creators of this plan for state employees, they never would have thought up this idea in the first place.

Lou Ann Adams
Co-owner, Zebulon Drug Company
Zebulon

BIZZELL CHOSEN PRESIDENT ELECT

Report of the Elections Committee

We, the members of the NCPhA Elections Committee, met today April 9, 1992 at the Institute of Pharmacy in Chapel Hill, to open, tally and record the ballots cast in the mail election.

These successful candidates will be installed in office at the Sunday morning Installation Program of the 114th Annual Convention in Pinehurst May 21–24.

The results of this election are:

For 1992-1993 President Elect

W. Robert Bizzell, Kinston

For Member of the Executive Committee for three year terms:

Rebecca Ann Wheeler, Charlotte

Pamela U. Joyner, Morrisville

The Election Committee

Jack K. Wier Jr.
LeRoy Werley Jr.

Melvin A. Chambers
Alfred H. Mebane

NORTH CAROLINA SOCIETY OF HOSPITAL PHARMACISTS NEWLY ELECTED OFFICERS

The newly elected officers of the North Carolina Society of Hospital Pharmacists are:

President – **Leslie Mackowiak**, assistant director of pharmacy, Duke University Medical Center, Durham;

President Elect – **Ronald Small,** director of pharmacy, North Carolina Baptist Hospital, Winston-Salem;

Board of Directors – **Dennis Williams**, clinical associate professor, UNC School of Pharmacy, Chapel Hill and

Timothy Giddens, director of pharmacy, Southeastern General Hospital, Lumberton.

We believe, like you do, that it's the little things in life that count.

As a pharmacist, you have the opportunity to really appreciate the little things that make life worth living every single day. The simple smile of trust from a customer, the infectious giggle from a child. The miraculous fact that one small pill can help keep a person healthy.

At Marion Merrell Dow, we know just how much you appreciate the little things. That's why we do them with each and every one of our products, to assure that the quality is there each and every time you dispense them.

Our quality control is, in fact, a series of little things, a special pattern of checkpoints that takes place before, during, and even after the manufacturing process.

For the best in pharmacy and in life, it's definitely the little things that count. That's why you can always count on Marion Merrell Dow.

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PRESCRIPTION PRODUCTS DIVISION
KANSAS CITY MO 64114

Your prescription for better business.

WILLIAMS NAMED 1992 OUTSTANDING APHA/ASP CHAPTER ADVISOR

Dennis M. Williams, Pharm.D. was named the recipient of the 1992 Outstanding American Pharmaceutical Association-Academy of Students of Pharmacy Chapter Advisor Award at the Annual Meeting of the American Pharmaceutical Association in San Diego. Williams was honored for providing leadership, inspiration and outstanding guidance to the UNC-Chapel Hill chapter, as well as encouraging student involvement in professional activities. The award was presented March 16, 1992.

This annual award, established in 1988, recognizes advisors of the APhA chapters of the Academy of Students of Pharmacy who have promoted with distinction and excellence the welfare of pharmacy students through various professional activities.

Born in Louisville, Kentucky, Williams is a graduate of the University of Kentucky College of Pharmacy where he received his B.S. in Pharmacy and Doctor of Pharmacy degrees in 1977 and 1981 respectively. He served as consultant to the Knott County Health Care Center while in Kentucky and has been a consultant to the Orange County (NC) Health Department since 1987. He also serves as consultant to the Health Sciences Consortium, developers and publishers of health care educational programs.

A member of the UNC Division of Pharmacy Practice faculty since 1985, Williams' interests are in pulmonary diseases and therapeutics. He has served as president of the Durham-Orange Pharmaceutical Association and on various committees of the North Carolina Pharmaceutical Association and the North Carolina Society of Hospital Pharmacists. He is a member-at-large of the APhA Academy of Pharmacy Practice and Management Section on Clinical/Pharmacotherapeutic Practice.

1992 APhA/Merck Student Pharmacy Project Grant Winners. Third from the right is Virginia Clay from Campbell University.

Photo by Oscar & Associates, Chicago

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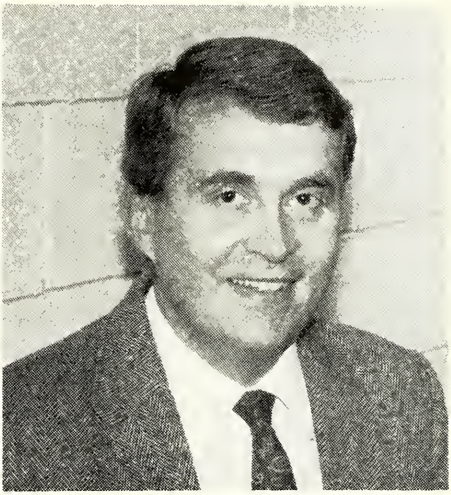
PHARMACY LAW CAPSULE

COMPOUNDING: AN ART OR LIABILITY?

by James A. Boyd, Pharm.D., M.B.A.
Assistant Professor,
Department of Pharmacy Practice
Campbell School of Pharmacy

Drug enforcement agencies, particularly the Food and Drug Administration (FDA), have recently intensified their focus on pharmacist compounding. Spurring FDA interest are serious and sometimes fatal injuries from incorrect formulations, which suggest some pharmacists have not utilized correct procedures or controls when compounding medication orders. A pharmacist in Pittsburgh, Pennsylvannia, compounded indomethacin eye drops which resulted in eye infections in 12 people, requiring an eye removal in two individuals. In Lincoln, Nebraska, patients died after receiving a contaminated surgical solution prepared by the hospital pharmacy. (*American Pharmacy*, Vol.NS31, No. 10, page 32)

As pharmacists, we know the degree of allowable error and adherence to aseptic techniques varies greatly depending upon the type of product compounded, or probably more precisely, the route of administration for which the product is intended. For example, a hyperalimentation solution administered directly into the subclavian artery requires a very high degree of accuracy and very strict adherence to aseptic techniques. Because of the susceptibility of the eye to infections, ophthalmics should be prepared very carefully. While external preparations like triamcinolone/eucerin require acceptable pharmaceutical technique, the procedures employed are not as stringent as those described above. A pharmacist's decision to compound a particular product should be primarily dependent upon the type of product, availability of proper equipment, and clear knowledge of proper technique.



James A. Boyd

Historically, and to some extent today, compounding has been an integral part of our profession. North Carolina, as well as many other states, include compounding in the definition of pharmacy practice. "Practice of Pharmacy means the responsibility for: interpreting and evaluating drug orders, compounding..." (*Pharmacy Laws of North Carolina*). The North Carolina Pharmacy Practice Act defines compounding as "taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packer."

When a pharmacist compounds a prescription, the final product must comply with the basic requirements set forth in the Food, Drug and Cosmetic Act (FDCA). The drug (and cosmetic) must be safe, effective, properly labeled, and free from adulteration. "Adulteration" describes a product which is filthy, putrid, decomposed or held in unsanitary conditions. By definition, the Act automatically considers a product to be adulterated if mixed, prepared, compounded, or stored in unsanitary conditions, (i.e., the product need not be actually adulterated to be "deemed" adulterated according to the Act).

The pharmacist who compounds a prescription or OTC product, or repackages an OTC product, assumes the responsibility for the integrity and labeling of the product, as well as the manner in which the product was prepared and stored prior to dispensing. One should also remember that the finished OTC product may be classified as a "New Drug" according to FDA's definition in the Act. A "New Drug" requires testing to ensure safety and effectiveness. Also, "New Drugs" must comply with the New Drug Application (NDA) process.

A prudent pharmacist should follow appropriate techniques in the practice of compounding; remembering to adhere to appropriate labeling requirements for prescription and non-prescription medications. Procedures are defined and available in resources such as Remington's *Pharmaceutical Sciences*, and the *U.S. Pharmacopoeia.* Despite the potential for litigation, compounding offers unique advantages to the patient. Dosages, vehicles and medications can be titrated and compounded to the individual needs of the patient. Pharmacists individually and collectively must protect the profession's interest in the art of compounding.

See next two issues of *Pharmacy Law Capsule*, "When Does Compounding Become Manufacturing" and "NABP Defines Compounding and Manufacturing."

(The author would like to point out that the distinction between Compounding and Manufacturing is a very complex issue, and it would be impossible to completely cover the topic in a few pages. The author would further state that many of the legal questions raised have not been answered. The intent of this article, and the articles in the next two issues, is to inform pharmacists about which state and federal administration agencies, such as boards of pharmacy and the FDA, are likely to develop new rules and regulations.)

FIRST DATABANK REPORT ON 1991 DRUG PRICE CHANGES

According to First DataBank, the California-based electronic drug database company, all classes of drug products had lower average increases than in 1990. Price increases slowed dramatically in 1991, with the price increase for the average product slipping to 7.5 percent versus 9.2 percent in 1990, the lowest figure since 1988.

Over 35 percent of legend pharmaceuticals had price increases in 1991, and the average product that changed increased 20.5 percent. In 1990, 42.4 percent had changes and those that changed increased 21.6 percent.

Anticonvulsants, anti-ulcer treatments, sedatives and tranquilizers were the therapeutic classes with the largest increases in 1991. Single source products increased faster than multiple source products. Pharmaceuticals from the top 25 manufacturers had the lowest overall increases.

The average price increase for a product from one of these top 25 companies dipped to 5.5 percent, two full points below the increases for the industry as a whole. These are many of the best selling products and account for a large percentage of drug sales. Over 60 percent of the products from these 25 manufacturers had price increases, but the average was only 9.1 percent—compared to the average increase of 12.3 percent for single source products.

Over 68 percent of single source products had price increases and the average change was 12.3 percent. Multiple source products increased on average 7.2 percent. Over 27 percent of multiple source products had increases and the average increase was 26.5 percent.

Barbiturates used as anticonvulsants led the major therapeutic classes with an average increase of 39.6 percent. Barbiturates used as sedatives had average increases of only 9.9 percent. GI products increased an average of 35.9 percent in 1991.

First DataBank maintains and distributes the National Drug Data File used by over 40 Medicaid programs.

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Pharmacist-Manager

Mac Keithan's Family Pharmacy
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Fayetteville
Chalmas Craig Stewart
Pharmacist-Manager

12/2/91

The Medical Park Pharmacy
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Cary
George Delon Dove
Pharmacist-Manager

12/16/91

Planned Parenthood of Orange & Durham
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Durham
Ned Wilson Griffin
Pharmacist-Manager

Impact Center of Asheville
50 Doctors Drive, Suite A-203
Asheville
James Allison Bradley
Pharmacist-Manager

Revco Discount Drug Center
565 Highway 49 N., Suite 150
Harrisburg
Edward Zebulon Morris Jr.
Pharmacist-Manager

1/20/92

R.C.P. Nursing Services
905 Brame Avenue
North Wilkesboro
Richard Gwyn Brame
Pharmacist-Manager

1st Rx Pharmacies, Inc.
1422 North Center Street
Statesville
Larry Norton Marlin
Pharmacist-Manager

1/23/92

Justus Pharmacy
303 N. Main Street
Hendersonville
Michael Victor Rogers
Pharmacist-Manager

1/31/92

Revco Discount Drug Center
212 North Main Street
Boiling Springs
Edward Vincent Beam
Pharmacist-Manager

2/3/92

Belwood Pharmacy
6033 Fallston Road
Lawndale
Teresa Teague Jackson
Pharmacist-Manager

2/12/92

Health & Medications At Home, Inc.
231 13th Avenue Place NW
Hickory
Emily Feagin Moseley
Pharmacist-Manager

Maple Hill Pharmacy
Old Maple Hill Road
Maple Hill
Randolph Fletcher Spainhour
Pharmacist-Manager

Penslow Pharmacy
North Dyson Street
Holly Ridge
Randolph Fletcher Spainhour
Pharmacist-Manager

2/17/92

Family Planning Program
Reynolds Health Center
Winston-Salem
Kenneth Charles Becker
Pharmacist-Manager

Wilson Pharmacy & Medical Supplies
5529 West Market Street
Greensboro
Thomas Steve Wilson
Pharmacist-Manager

2/27/92

Wally's Pharmacy
Rockford Street
Mount Airy
Wallace Allen Johnson
Pharmacist-Manager

3/4/92

Townsend's Pharmacy
111 South Main Street
Red Springs
James Craig Bell
Pharmacist-Manager

3/10/92

Moose Drug Company
101 West Franklin Street
Mount Pleasant
William Whitaker Moose Jr.
Pharmacist-Manager

3/16/92

Insticare Pharmacy
212 West Church Street
Nashville
James Michael Sykes
Pharmacist-Manager

Highlands Pharmacy
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Highlands
Sherry Denise Hendrix Sims
Pharmacist-Manager

The Medicine Shoppe
640 Merrimon Ave. Unit 106
Asheville
John Aloysius Boff
Pharmacist-Manager

General Store Discount Pharmacy
6360 Hwy 150 East
Sherrills Ford
John Michael Felts
Pharmacist-Manager

Upchurch I.V. Therapy Corp
5112 N Roxboro Rd
Durham NC
David Emmett Upchurch
Pharmacist-Manager

Revco Discount Drug Ctr
5383 Shattalon Drive
Winston-Salem
Ruth Whitlow Mitcham
Pharmacist-Manager

DICKINSON'S PHARMACY

YOUR WINDOW OF OPPORTUNITY

Never have pharmacists had a better chance to seize control than they have in this extraordinary election season. It's a window of opportunity that may not be open long, or again.

The key is the national health debate, which this time is much more than political clap-trap.

This time, literally everybody is talking and worrying about it.

That fact is every pharmacist's cue to step forward and throw light into the tangled thicket of self-serving rhetoric that's confusing everybody.

Pharmacists have a simple message to get across to the public, and hundreds of opportunities each day to do it: Support the health plan that guarantees to keep the neighborhood pharmacies open-that is, the plan that guarantees freedom of choice of provider.

Since few of the options being touted by candidates and special interest groups will likely do this, it's up to the pharmacist to keep this simple message from getting lost, through posters and signs, bagstuffers, local media ads, etc.

But like a lot of simple messages, this one needs some not-so-simple support, since pharmacy as a whole has done such a bad job over the years in demonstrating why a personal pharmacy is important.

This is where the "opportunity" part comes in. Nobody promised you a rose garden. Opportunities take work to come into full bloom.

As all the political hype about health care heats up, pharmacists can be demonstrating their one-on-one importance as neighborhood health resources.

They can do this by seizing all opportunities to counsel, engaging in conversations about all aspects of health care, establishing a library/information center (PDR, USP-DI, health news clips, pharmacy literature) in a conspicuous corner, placing appropriate health messages throughout the store, and promoting aggressively in the community through print and air media, direct mail and cooperative displays in other health professionals' offices.

That's the hard part, of course. But nothing good ever came easy.

Signs that explain pharmacy pricing structures, showing manufacturer price increases and dispensing fee freezes, and comparing these to insurance company administrative costs (as high as 40% of premiums), can help patrons understand whose side you're on, and why.

Communications techniques shown in NARD's excellent free manual, *Ideas That Work*, can be used to great effect.

Try to engage local candidates in a debate, with the help of some patients you have helped motivate. The local news media will be interested in covering your call to debate, and this will help provid additional pressure on the candidate to agree.

When Waverly, Tennessee pharmacist Bob Phelan got a positive written reply from his state's Senator Jim Sasser on the discriminatory pricing issue, he bought a half-page ad in a local paper to display it, along with his question, "What do you think?"

The local response from supportive readers deluged Phelan for days and made him something of a celebrity, as well as an authority on health issues.

As recognition grows for your role as your community's local protagonist for better health care, the simple message of supporting the freedom of choice option in any proposed health plan will make more and more sense.

Patients will more easily see the pharmacy as an important asset to the community. Anything that even seems to threaten it will tend to be rejected.

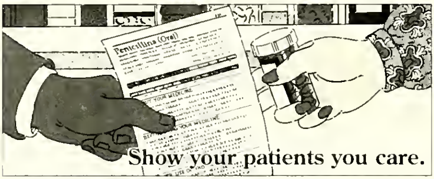
Pharmacy's audience for this effort is vast and unusually attentive now. The window of opportunity gapes wide.

This can be pharmacy's cue to take control of its own destiny at last.

CAMPBELL ASP CHAPTER WINS APHA/MERCK PHARMACY GRANT

Congratulations to Campbell University Academy of Students of Pharmacy chapter, recipients of a $2,000 grant from the APhA/Merck Pharmacy Grant program. The announcement of awards to Campbell University and three other schools of pharmacy was made during the 139th Annual Convention of the American Pharmaceutical Association in San Diego.

The Campbell project is "Health Promotion–Disease Prevention, A Pharmacy School's Approach to Wellness." The plan is to provide an opportunity for pharmacy students and faculty of Campbell University School of Pharmacy to become motivated and better prepared to provide health promotion/disease prevention services in practice settings and communities.


Penicillins (Oral)
Show your patients you care.

Provide them with USP's personalized drug education materials.

USP's Patient Education Leaflets are the ideal take-home supplements to your patient counseling efforts.

Now it's easy to provide your patients with the personalized drug education counseling they want and need...thanks to USP's Patient Drug Education Leaflets.

These easy-to-understand, 5 1/2" x 8 1/2" fliers cover such vital topics as guidelines for proper usage, major precautions, and selected side effects. Available in 88 titles covering 2,000 of the most commonly prescribed drugs, USP Leaflets include space for customized patient and pharmacy information.

Choose from three convenient formats.

- Individual leaflet pads of 50 sheets.
- InstaPak kits that include 44 pads of 50 leaflets each plus ready-to-display counter tray.
- USP Leaflet Diskette Version 3.5 that enables you to generate personalized USP leaflets whenever you need them on any IBM or IBM compatible PC.

Order these beneficial patient counseling materials today. Proceeds help support your State Pharmacy Association.

Watch for a complete listing of USP Patient Drug Education Leaflet titles and an order form from your State Association.

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* For Leaflet Diskette orders add $7 for shipping and handling
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NORTH CAROLINA CHAPTER OF THE AMERICAN SOCIETY OF CONSULTANT PHARMACISTS

More than 150 North Carolina pharmacists are members of the American Society of Consultant Pharmacists. In October 1991, a North Carolina Chapter of ASCP was established to conduct ASCP business, programs and activities on a statewide level. All members of ASCP in this state are automatically members of the North Carolina Chapter.

The North Carolina Chapter met in Charlotte March 28, 1992 during the Fourth Annual Post–Graduate Workshop for Consultant Pharmacists. Fifty members attended and committees met for the first time to discuss responsibilities and accept charges.

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FAX 703-486-2997

For more information about the North Carolina Chapter of ASCP, contact:
Frank Fletcher III
106 Woodrow St.
Fayetteville NC 28303
800-584-6487

PROPOSED CHANGES AND ADDITIONS TO

ARTICLE 4A

NORTH CAROLINA PHARMACY PRACTICE ACT

§ 90-85.3 Definitions

(m) "Patient counseling" is the face-to-face, oral transfer of information to a patient (or the patient's agent) at the time a prescription is provided by a person authorized to dispense drugs under North Carolina law .

Counseling may include, but is not limited to,

1. The name, strength, route of administration and dosage form of the medicine,
2. The storage of the medicine.
3. The directions for use and duration of therapy,
4. Refill instructions,
5. What to do if a dose is missed,
6. Common side effects to look for and what to do if they occur,
7. Possible interactions with food and other medicine (including non prescription medicine.)
8. Special directions for preparation, administration and/or use by the patient
9. Instructions for self-monitoring of therapy.

Written materials, audio visual aids, signs, patient leaflets and other educational materials may be a supplement to, but do not replace, counseling.

§ 90-85-32 Filling and refilling regulations.

(b) The authorized dispenser must offer to counsel the patient on all prescription orders. Such offer shall be made in person, whenever practicable, or by telephone.

All counseling shall be done in the manner most appropriate to the specific patient and subject to the professional judgement of the authorized dispenser.

Patient counseling pursuant to this Article shall impose no additional liability upon the authorized dispenser arising from the rendition of this service.

Nothing in this section shall be construed as requiring an authorized dispenser to provide counseling when the patient (or the patient's agent) refuses such consultation.

(c) Reasonable effort must be made to obtain, record and maintain at least the following patient information:

1. Name, address, telephone number, gender and age or date of birth,
2. Current list of medicines and devices relevant to drug therapy being used,
3. Relevant disease states
4. Allergies and drug reactions
5. Comments relevant to the patient's medication therapy.
6. Any other information necessary to provide counseling.

To comply with the Omnibus Reconciliation Act of 1990 as it relates to Medicaid and patient counseling, NCPhA President Betty H. Dennis appointed a Task Force of all elements of pharmacy to develop mutually acceptable language to be incorporated in the NC Pharmacy Practice Act. This is the result and will be introduced in the NC General Assembly when it convenes in late May. Your support is needed for this to be passed without serious modification. There are some in pharmacy who may have problems with this concept and we urge them to contact NCPhA with any questions.

ACROSS THE STATE

This column features news briefs about people, places and events related to pharmacy in North Carolina, and also about North Carolina pharmacists and other friends of pharmacy who must be out of the Tar Heel State for one reason or another. The NCPhA staff and The Journal's *Editorial Advisory Board welcome and solicit your contributions to this column. Photos (black and white, preferably) are also welcome. Send us your news!*

The Guilford County Society of Pharmacists met Sunday night, February 9, 1992 at the Greensboro AHEC in Moses H. Cone Memorial Hospital. Featured speaker was Wallace Chi-li Wu, M.D., Professor of Medicine, Bowman Gray School of Medicine, Winston Salem, N.C. "New Advances in the Management and Treatment of High Risk Patients Using Non-steroidal Anti–inflammatory Agents" was the topic of Dr. Wu's presentation.

Olin H. Welsh, UNC 1951, District Sales Manager for Wyeth-Ayerst Laboratories, was honored by friends, colleagues and family on the occasion of his retirement. Welsh had worked for 40 years in retail and hospital pharmacy, and pharmaceutical sales and management. Faye and Olin will retire in Lumberton.

Sybil Austin Skakle, Chapel Hill pharmacist and NCPhA member, is featured in the December 1991 issue of *The State* magazine. Skakle wrote the article "The Legacy of Billy Mitchell" which appears on page 14 of this issue. She is the subject of "One Last Word" which is the final feature in the magazine on page 46

Congratulations to Al Lockamy, Raleigh, on his election to a two-year term as member-at-large of the American Pharmaceutical Association Academy of Practice and Management Executive Committee. Al is currently serving as an APPM section chairman and is an APPM Fellow.

Congratulations to Pam Joyner, Morrisville, on being selected as the North Carolina Society of Hospital Pharmacists 1991 Pharmacist–of–the–Year. The announcement of this award was made at the Society's Awards Banquet during the Winter Meeting in Charlotte. Pam has served the Society in many capacities, including 1988 President.

Ed Lowdermilk of Chapel Hill was recently honored by the Occoneechee Council of the Boy Scouts of America as he received the Silver Beaver Award, the highest award that can be given to an adult by Scouting.

Lowdermilk has served as Scoutmaster of Troop 449 for the past 14 years and has had fifteen Eagle Scouts during that time, including four Eagles in the past year. He was voted Scoutmaster of the Year from the Orange District in 1991.

He also serves as Advisor to the Eno Chapter of the Order of the Arrow, a group of older scouts, and received the Vigil Honor by that group for his efforts in 1991.

He is currently president-elect of the East Chapel Hill Rotary Club.

He is a founding member and officer in the Reformed Church of Chapel Hill.

Roy O. Lewter, Kernersville, has been elected assistant vice president of professional services at Crown Drugs Inc. Lewter is a graduate of the University of North Carolina School of Pharmacy . Lewter joined Crown in 1965 as a part-time employee.

Chuck and **Beth Keiger Helpingstine** and their son Chase announce the birth of Victoria Joanne on October 26, 1991 in Chapel Hill. Beth is a 1985 graduate of UNC's School of Pharmacy.

Pharmacist **Sherry Sims** and her husband, David, recently purchased the Highlands Pharmacy in Highlands, NC. The pharmacy was sold by Jack Alexander, who was the owner for almost 20 years. Alexander will remain with the pharmacy on a part-time basis for a period of time. He said he hopes to see all his old friends from time to time. The Sims are natives of Athens, GA, who now claim Highlands as home. They expect to become active in community and civic affairs.

After 27 years as owner of Lowell Discount Drug, Gordon Bane is taking a self-prescribed retirement. Bane purchased the 71-year old establishment in 1964 in a double deal in which he agreed to purchase the former owner's home as well. Harold Hearne, who delivered newspapers to Bane's house many years ago, is purchasing the store. "I was all worn out," said Bane, who often worked 60-hour weeks. "The hardest thing I ever did was sell the business. It was hard to let go."

Police ponder the motives behind robberies of three Eckerd Drug stores in Burlington. Over $2000 worth of boxes of Monistat cream and suppositories and Gyne-Lotrimin cream and suppositories were stolen in the separate events. The reasons for the thefts remain unclear. The products are useless for anything but what they are sold for, said a Burlington Lieutenant Detective.

The Medical Park Pharmacy of Cary, located in the Medical Park of Cary, opened recently. The store, operated by **Delon** and **Douglas Dove**, will offer delivery and consultation services for medications.

Cindy Bishop of Charlotte was awarded the Ciba-Geigy Leadership Award along with the Squibb Past Presidents Award by the North Carolina Society of Hospital Pharmacists. Bishop is presently the assistant director of pharmacy at Gaston Memorial Hospital.

Terri M. Little of Burlington has been honored by the North Carolina Society of Hospital Pharmacists with a Certificate of Appreciation for Outstanding Service and Dedication.

The following persons were among the recipients of the Award for Continuing Excellence in 1991 given by the North Carolina Society of Hospital Pharmacists: **T. Donald Marsh,** director of pharmacy education in the Mount Area Health Education Center, Asheville; **Dan Garrett**, director of pharmacy at Memorial Mission Hospital, Asheville; **Beverly Holcombe**, clinical specialist at UNC Hospitals, Chapel Hill; **Frances Gualtieri**, director of infusion therapy, UNC Hospitals, Chapel Hill; **Christine Rudd**, assistant director for clinical services at Duke University Medical Center, Durham; **Dennis Williams,** clinical associate professor at the UNC School of Pharmacy,Chapel Hill; and **Timothy Ives**, associate professor at UNC School of Pharmacy, Chapel Hill.

Daniel Teat of Buies Creek has been selected by the North Carolina Society of Hospital Pharmacists to receive the Continuing Education Award. This is the third year Teat has received the award which is given to a pharmacist who provides outstanding service to both pharmacy and public health. Teat is a graduate of the Bachelor of Science and Doctor of Pharmacy programs at Mercer University in Georgia. He is currently the director of admissions and continuing education and assistant professor at the Campbell University School of Pharmacy.

Steve Fuller, director of pharmacy education in the Fayetteville Area Health Education Center, and Steve Dedrick, associate director of pharmacy at Duke University Medical Center, were honored with the Presidential Service Awards by the North Carolina Society of Hospital Pharmacists at the annual winter meeting.

CORRESPONDENCE COURSE

SMOKELESS TOBACCO PRODUCTS: TRENDS, TOXICOLOGY, AND PHARMACIST INVOLVEMENT

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Goals

The goals of this lesson are to: discuss current trends in the use of smokeless tobacco, relate product use to specific health risks, and suggest points to convey to consumers who are interested in undertaking a cessation program.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. Identify trends in the use of smokeless tobacco products;
2. choose the correct terminology that relates to smokeless tobacco use, and pathology associated with it;
3. select specific health risks associated with smokeless tobacco use and explain the pharmacologic/toxicologic basis for the risk, when known; and
4. demonstrate knowledge of suggested information to convey when counseling consumers on smokeless tobacco use.

Tobacco is addicting! It makes little difference whether it's smoked, macerated in the mouth, or sniffed into the nose. Tobacco, specifically nicotine, is as addicting as opioids, cocaine, or other illicit drugs of abuse.

Many users report that they partake of smokeless tobacco because they enjoy its taste. In fact, a recent study concluded that it was harder to quit smokeless tobacco use than to stop smoking cigarettes.

This article will help pharmacists become more knowledgeable about smokeless tobacco products. It discusses contemporary trends in their use, and suggests reasons for them. It identifies specific pathologies associated with its use, and lists the pharmacologic/toxicologic rationale for these changes, when known. It also discusses activity underway to limit the use of these products. For users who express an interest in learning more about the products and their adverse health consequences, it provides specific information for pharmacists to convey to them.

Historical Perspectives

Tobacco was used by native Americans long before Columbus first visited the New World. Indian folklore dates its use back at least another 500 years, and information from archeological discoveries suggests that tobacco may have ben cultivated in North and South America as early as 5000 B.C.

With its introduction to Europe and the rest of the world by early voyagers, tobacco use was a colorful part of history. This is certainly true of smokeless forms. Tobacco leaves were pounded into fine powders for sniffing deep into the nostrils, and minced into coarse cuts for chewing or holding in the mouth. A large percentage of the world's population over the years reportedly learned that tobacco conferred a variety of pleasurable and/or medical sensations, and they spent many hours each day chewing, sniffing, snorting, or smoking tobacco.

Its medical applications were of special interest. Smokeless tobacco products were recommended as first-line therapy to combat a variety of the ills of the day, including gastrointestinal afflictions, toothache and nasal congestion. An advertisement of years-gone-by proclaimed: "My nose is all stopped up I fear! It needs a dose of snuff to clear."

Use by Americans flourished throughout the 19th century and into the first decade of the 20th. But strong opposition was mounting regarding possible adverse health consequences of disposing of the major by-product of smokeless tobacco use—saliva—in public places.

By then science had linked spitting with tuberculosis, which was a major cause of death at that time. Opponents publicly proclaimed dissatisfaction with users who required a place to expectorate their spittle. It became socially unacceptable and illegal to spit in many public places.

The movement against use continued, and ultimately opponents won their battle in 1913 when the first commercially manufactured American cigarette, Camel, appeared on the scene. This, along with the cigarette rolling machine, offered smokeless tobacco users a relatively inexpensive alternative form of tobacco that didn't requirespitting or the use of cuspidors. There was a massive switch to smoking, and cigarettes largely supplanted smokeless tobacco product use.

With the Surgeon General's proclamation a half-century later that smoking may be injurious to health, and mounting evidence that smoking is the primary preventable cause of death in America, many smokers were led to believe that unlit tobacco was safer than tobacco that was burned. Manufacturers of smokeless tobacco products recognized an emerging fertile market. They directed advertising efforts at conveying the image that a user was a strong, rugged, machismo all-American hero, tactics that are still used today.

In the early 1970's, millions of Americans, including a whole new generation of users—teenagers—began to use the products in record quantity. It is also tempting to speculate that the popularizing of styrofoam cups at that time also helped bolster smokeless tobacco use. They provided a portable, disposable cuspidor.

Who Uses Smokeless Tobacco and Why?

In earlier years smokeless tobacco users were often pictured as uneducated "shoeless hillbillies" of low economic and social status from poor regions of the country. If this description were formerly true, it is now obsolete. Today, users represent all socioeconomic and educational classes. They live in all parts of the country, although use is greatest in the South, and lowest in the Northeast.

Terminology that describes products and their use is defined in Table 1.

Prevalence of contemporary use can be estimated from sales, increasing about 11 percent per year since 1970. In 1986, annual sales of smokeless tobacco products in the U.S. exceeded $1 billion. Sales of moist snuff were more than 30 percent higher than five years earlier, while chewing tobacco sales declined by 3.5 percent, and dry snuff sales remained constant. Moist snuff is now the predominant form used in America.

In the early 1970's, the majority of users were elderly men. Today, reports are common that up to 30 to 40 percent of adolescent males use smokeless tobacco. One national survey indicated that 60 percent of males between 12 and

Table 1
Smokeless Tobacco Terminology

Snuff: Loose, ground-up, dry ("Scotch") or moist ("Snoose") tobacco. Processed as a flavored, sweetened, salted and/or scented product. Sold in loose form, either packed in cans or in "tea-bag" pouches.

Chewing tobacco: Loose-leaf tobacco, marketed in a large, folding pouch.

Chaw: A golf ball-size wad of leaf or plug tobacco. The amount of tobacco removed from pouch with thumb, index and middle fingers.

Dip: See "Snuff dipping"

Plug tobacco: Compressed leaf tobacco sweetened with molasses, licorice or sugar, and sold as flat bars or rolls.

Twist tobacco: Stemless tobacco leaves. Marketed as lightly twisted rolls.

Snuff dipping: Practiced by securing a pinch of loose, ground tobacco between the thumb and forefinger, and placing a dip (small portion of tobacco) between the cheek and gum and sucking the quid (moistened tobacco). Once in the mouth, the quid is generally confined to one area.

17 years of age had used smokeless tobacco during the previous year.

The percentage of use within age groups declines with increasing maturity; the number of users in their 40s and beyond has decreased. It is clear that the use of these products is a trend of younger Americans. Tragically, wide usage is reported in pre-adolescents. Up to one-half the number of elementary schoolboys surveyed uses smokeless tobacco, many of them at very young ages.

In America, the use of smokeless tobacco is primarily a habit of white males. Females seldom use it. The typical user dips or chews 2 to 8 times per day, for a total of 3 hours.

Results of a questionnaire answered by 5,894 college students and published in 1989 revealed other interesting statistics. Twenty-two percent of men and 2 percent of women were users. Asked why they used smokeless tobacco, 66 percent said they liked it. Another 23 percent admitted they were addicted. The remainder said it made them look grown up, or they used it socially because of friends.

It's interesting that professional athletes, notably baseball players, inadvertently promote the products among young people. A 1987 survey of 25 teams in both major leagues revealed that 46 percent of players, 35 percent of managers and coaches, and 30 percent of trainers use these products. Product containers are often visible in uniform pockets as well as a chaw in their mouth. Young sports fans wish to emulate their heroes, and believing that product use is acceptable, try it themselves. Then, they're hooked!

The National Collegiate Athletic Association (NCAA) reports that 31 percent of professional athletes from many different sports actually started using smokeless tobacco during or after their freshman year in college.

Physiologic and Pathologic Changes Associated with Smokeless Tobacco

Cigarette smoking poses a greater danger to health than unburned tobacco, but use of the latter is not without risk. The Surgeon general reported in 1979 that "...snuff and chewing tobacco have not been found to increase mortality (either overall or cause-specific) in the United States." By 1982, the annual report stated that long-term use of snuff appeared to be a factor in the development of cancers of the oral cavity.

Today, there are still many more questions than answers about physiologic and pathologic changes associated with use of smokeless tobacco. Some known facts are listed in Table 2.

Gingival Recession. Common among smokeless tobacco users, gingival recession, the wasting away of gum tissue, occurs in up to 60 percent of teenage users. Gingival recession is site-specific, with tissue migration such that tooth roots are exposed. This increases tooth sensitivity, and exposes root surfaces to the vulnerability of decay. Gum tissue doe s not regenerate. It can only be repaired surgically with great difficulty, if at all.

Gingivitis. Gingivitis is defined as clinically detectable acute or chronic, local or general, inflammation of the gums (gingiva). Data relating gingivitis to smokeless tobacco use are scarce and conflicting.

Oral Mucosal Pathology. There is a definite association between oral mucosal pathology and smokeless tobacco use. Leukoplakia is a leathery, wrinkled-appearing lesion with white striae and deep fissures. Lesions are sometimes elevated, and diffusely demarcated from surrounding mucosa. They are often asymptomatic. The literature recognizes the terms "snuff dipper's keratosis" and "snuff dipper's patch" as leukoplakia.

Leukoplakia lesions are precancerous, with a malignant transformation rate of about 18 percent. Two studies of high-school students confirmed the incidence of leukoplakia plaques from use to be 43 to 62 percent. Lesions form most commonly in the oral cavity at the site of quid placement, and in heavy and long-term users.

Oral Cancer. The first positive link between smokeless tobacco and oral cancer appeared in 1915. Another 646 documented cases were cited in the medical and dental literature between 1915 and 1972. Recently, the Surgeon General reported that its use increases the risk of cancer of the gingiva and buccal mucosa by 50 times.

Table 2

Physiologic and Pathologic Consequences of Smokeless Tobacco Use

- Discolored teeth and restorative material
- Decreased ability to taste and smell
- Bad breath
- Tooth loss
- Excessive tooth surface wear
- Slower healing of cuts and sores in mouth
- Gingival recession
- Gingivitis
- Oral mucosal lesions (e.g., leukoplakia)
- Oral cancer
- Systemic effects
  - Cardiovascular
  - Metabolic
  - CNS
  - Endocrine
- Addiction to nicotine
- Fetal and neonatal toxicity

The data for adversity are stronger for snuff, than chewing tobacco. Nearly 90 percent of oral cancers are linked clinically to tobacco use. Typically, users who develop oral cancer have a long history of heavy use; but in some cases, oral cancer develops with short-term use. The most common site is the buccal mucosa.

There are an estimated 25,000 new cases of oral cancer discovered each year, with more than 9,000 deaths. The most common type is squamous cell carcinoma, an aggressive lesion with a mortality rate of 40 to 50 percent within five years of diagnosing. Fortunately, oral cancer has a low malignant transformation rate. Disfigurement and disability are common in survivors.

Nitrosamines are the principle known chemical carcinogens in smokeless tobacco products. Formed during the processing of tobacco and when tobacco interacts with nitrite in saliva, nitrosamines are among the most toxic of all chemicals. They are alkylating agents that induce neoplasia at the site of contact with tissue. FDA prohibits sale of food amd beverage products if nitrosamine levels exceed 10 parts per billion (ppb). Concentrations of nitrosamines at 5,900 to 289,000 ppb are reported in various brands of smokeless tobacco. There is no government restriction on their sales.

In addition to the 19 nitrosamines identified, other carcinogens have also been isolated. Three toxic radioisotopes include Polonium-210, Radium-226, and Lead-210.

Whether cancer at sites other than the mouth can be linked to smokeless tobacco is currently inconclusive. There is a strong correlation between digestive and respiratory tumors, and its use. But evidence is less convincing than for oral cancer.

Tooth Decay. Anecdotal evidence has associated the use of smokeless tobacco with both increased and decreased prevalence of dental caries. Products may contain a high concentration of carbohydrate which bathes the teeth with cariogenic sugars and promotes tooth decay. Severe, degenerative changes in salivary glands and ducts have been noted. If these structures are significantly affected, the resulting reduction in salivary flow would increase susceptibility to dental caries. Firm evidence of this relationship is still lacking.

Early-on in smokeless tobacco product use, salivary flow is enhanced. Increased saliva helps protect against tooth decay. Moreover, the products contain fluoride, which is carioprotective. It is therefore difficult to assess the role of smokeless tobacco in development of caries.

Systemic Effects. Regular users may not realize there are numerous systemic effects associated with smokeless tobacco use. Nicotine is the ultimate cause of disease. The alkaloid is rapidly absorbed across the oral mucosa to reach peak blood concentrations comparable to those from smoking, and is distributed throughout the body. Blood levels are also more sustained than following cigarette or cigar smoking. An average absorption of 4.5 mg nicotine from chewing tobacco and 3.6 mg from snuff is expected. An average of 1 mg nicotine is absorbed per cigarette.

Pharmacologic effects of nicotine are complex and extensive. In general, actions are consistent with activation of the sympathetic nervous system. Cardiovascular effects include an increased heart rate of 10 to 20 beats/minute, and blood pressure of 5 to 10 mm Hg.

Prostacyclin synthesis is inhibited, and may enhance blood coagulation.

Metabolic actions result from elevated levels of circulating catecholamines which may contribute to increased total cholesterol and reduced HDL levels. On the central nervous system, arousal or relaxation, electroencephalographic changes and tremor are noted. Endocrine actions include increased growth hormone release.

Smokeless tobacco products can be a rich source of sodium (Table 3). Since some people use one or more containers of product each day, the amount ingested can be significant.

As indicated earlier, tobacco is addicting. In studies of teenagers who attempt to quit smokeless tobacco usage, only a small number are able to do so. Although users report serious adverse consequences, they continue to use the products. Some even relate using smokeless tobacco during sleep. Withdrawal symptoms begin within hours of cessation. Former users continue to crave the products.

Fetal and Neonatal Toxicity. Tobacco contains toxic substances including nicotine, lead and cadmium, that can injure the fetus. These same toxins reach significant concentrations in breast milk and can be injurious to suckling infants.

Fighting the Battle

There are numerous educational programs underway to curb the expanding use of smoke-

Table 3

Sodium Content of Selected Smokeless Tobacco Products*

	Container size (Gm)	Sodium/container (mg)
Snuff		
Copenhagen	34	1078
Happy Days Mint	34	1201
Kodiak	34	1126
Skoal	34	1150
Loose-leaf		
Beech-Nut	85	829
Big Red	85	822
WB Cut	34	1044
Plug		
Bloodhound	45	795
Brown's Mule	45	533
Days-O-Work	70	1020

*NEJM 312:919, 1985

less tobacco. These are sponsored by various groups such as the American Cancer Society.

In February, 1986, President Reagan signed into law "The Comprehensive Smokeless Tobacco Health Education Act" (PL-99-252). This legislation banned television and radio advertising for smokeless tobacco products. It directed the Secretary of HHS to inform the public of the dangers of smokeless tobacco, and help state officials to do likewise. PL-99-252 also required manufacturers to report annually to the Secretary the ingredients in smokeless tobacco products, particularly chemical additives. It established 18 years as the minimum age for purchasing the products. And, it required manufacturers to display one of three rotating label warnings of health hazards on each product package and advertisement; "Warning: This product may cause mouth cancer," "Warning: This product may cause gum disease and tooth loss," and "Warning: This product is not a safe alternative to cigarettes."

How About Quitting Smokeless Tobacco Use?

A report published in 1986 concluded it was more difficult to stop using smokeless tobacco products than cigarettes. Recall, a majority of users in one national survey admitted they enjoyed the taste of the products.

A sizeable number of users apparently do want to quit, or have thought seriously about doing so. A survey indicated that 56 percent of users would try to quit within the next year. Forty-one percent of dental patients said they would be receptive to dentists' or hygienists' advice to quit. And 28 percent of high school males showed an interest in quitting.

Pharmacist's Challenge

Health professionals, educators, parents, and school children need to be informed about adverse health effects associated with smokeless tobacco use. Pharmacists may wonder what they can do to help curtail continued growth of the smokeless market, especially since the predominant use of products is by young people. They can refuse to sell the products in their pharmacy. But that alone will not reverse current trends or stop usage since the majority of sales are transacted in non-pharmacy outlets. At minimum, electing to not supply the products sends a message to the community that shows pharmacists are interested in the good health of its citizens. The high level of public trust in pharmacists could be elevated even more.

There is a challenge for pharmacists; many users, especially younger ones, want to quit. Educational programs can be sponsored to make users aware of the health consequences. As part of community programs designed to inform about legitimate and/or illegitimate drugs, smokeless tobacco products could be included. Local branches of the cancer and heart associations, and the local dental association, can provide a vast resource of information on the topic. Taken into primary and secondary schools, such programs may make a significant impact on young people, and perhaps convince them it is not healthy to use the products.

A professional development program made possible by an educational grant from

SEARLE

For those users who cannot or do not wish to quit, two important points need to be conveyed. They should understand the importance of good oral hygiene. Also, they should vary the location of tobacco placement in their mouth to reduce the chance for oral pathology development. Much of the damage from smokeless tobacco products is due to placement of the quid at the same spot and leaving it there.

Will Nicorette help as an aid to smoking cessation programs? Nicorette is effective in assisting smokers to stop. While not officially indicated in smokeless tobacco cessation programs, there is support in the literature for its use.

Addiction to all tobacco products is due to nicotine. Nicorette provides nicotine while the user copes with the pharmacologic, sociologic and behavioral aspects of nicotine withdrawal. Therefore, the product may deserve a trial in cessation programs.

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CORRESPONDENCE COURSE QUIZ

Smokeless Tobacco

1. Historically, strong opposition that mounted against the use of chewing tobacco in the early 1900's resulted when spitting was linked to the spread of:
   a. influenza.
   b. polio.
   c. scarlet fever.
   d. tuberculosis.

2. One of the toxicities caused by smokeless tobacco is a leathery, wrinkled-appearing lesion of the oral mucosa. The term that best defines this condition is:
   a. hyperplasia.
   b. leukoplakia.
   c. nicotine necrosis.
   d. cellulitis.

3. The most common site for smokeless tobacco-induced oral cancer is the:
   a. buccal mucosa.
   b. juncture of the gums and teeth.
   c. side of the tongue.
   d. uvula.

4. The predominant form of smokeless tobacco used in the U.S. is:
   a. chewing tobacco.
   b. dry snuff.
   c. moist snuff.
   d. plug tobacco.

5. According to the chart in the article, the sodium content per container of snuff is reported to be in the range of:
   a. 0–499 mg.
   b. 500–999 mg.
   c. 1000–1499 mg.
   d. 1500–1999 mg.

6. Which of the following poses the greater danger to health?
   a. Cigarette smoking
   b. Smokeless tobacco

7. Gingivitis refers to inflammation of the:
   a. gums.
   b. lips.
   c. teeth.
   d. tongue.

8. In the survey reported in this article, the leading reason given by respondents on why they used smokeless tobacco was:
   a. it made them look grown up.
   b. they were addicted to it.
   c. social pressures.
   d. they liked the taste.

9. After snuff has been placed between the cheek and gum, the moistened tobacco that results is called the:
   a. chaw.
   b. plug.
   c. cud.
   d. quid.

10. Nicotine absorbed from smokeless tobacco products causes all of the following actions EXCEPT:
   a. increased heart rate.
   b. increased blood pressure.
   c. increased prostacyclin synthesis.
   d. increased circulating catecholamines.

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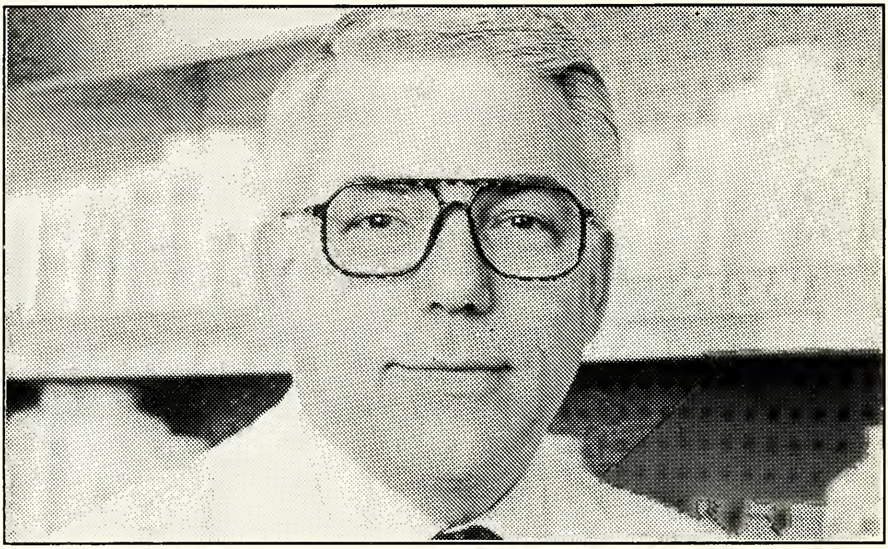

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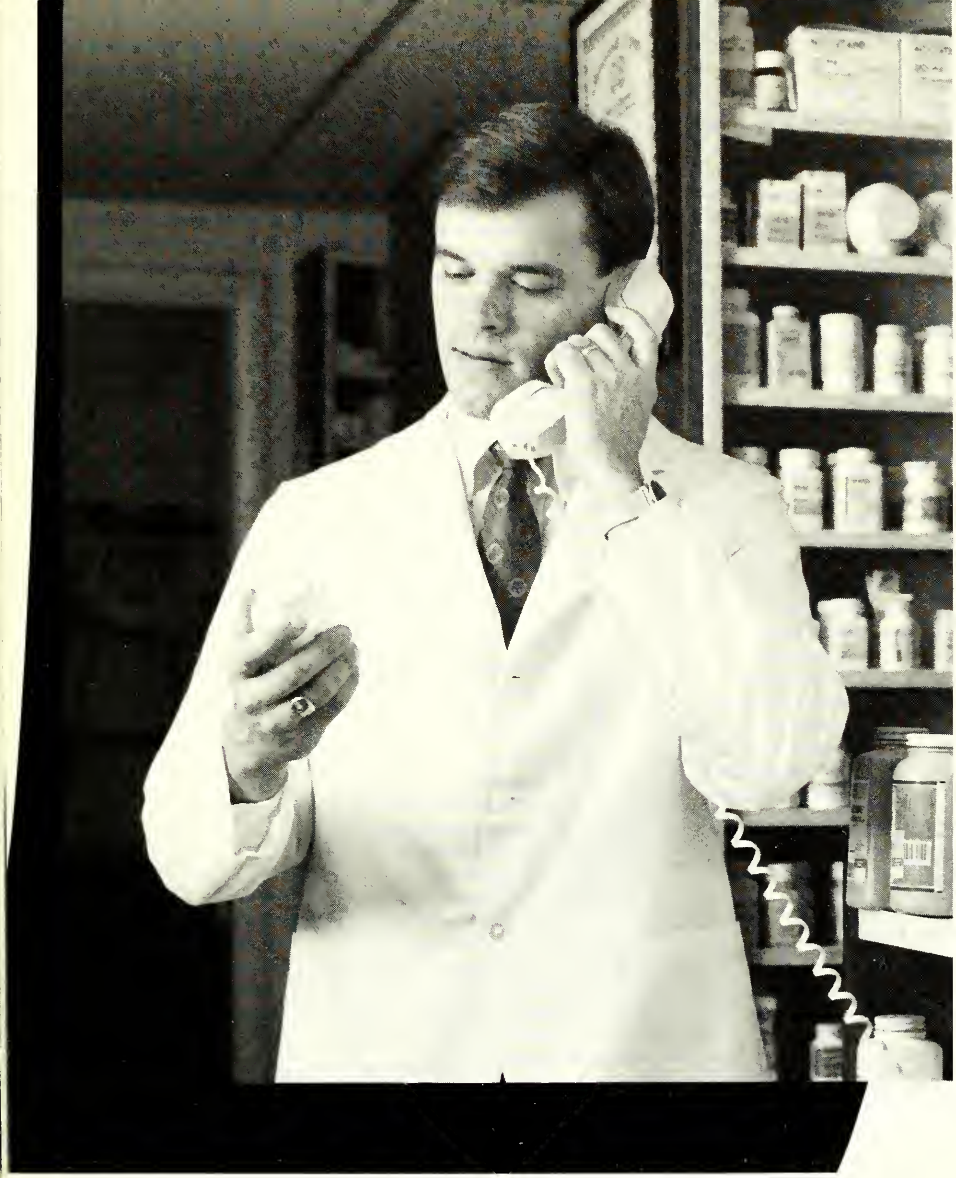

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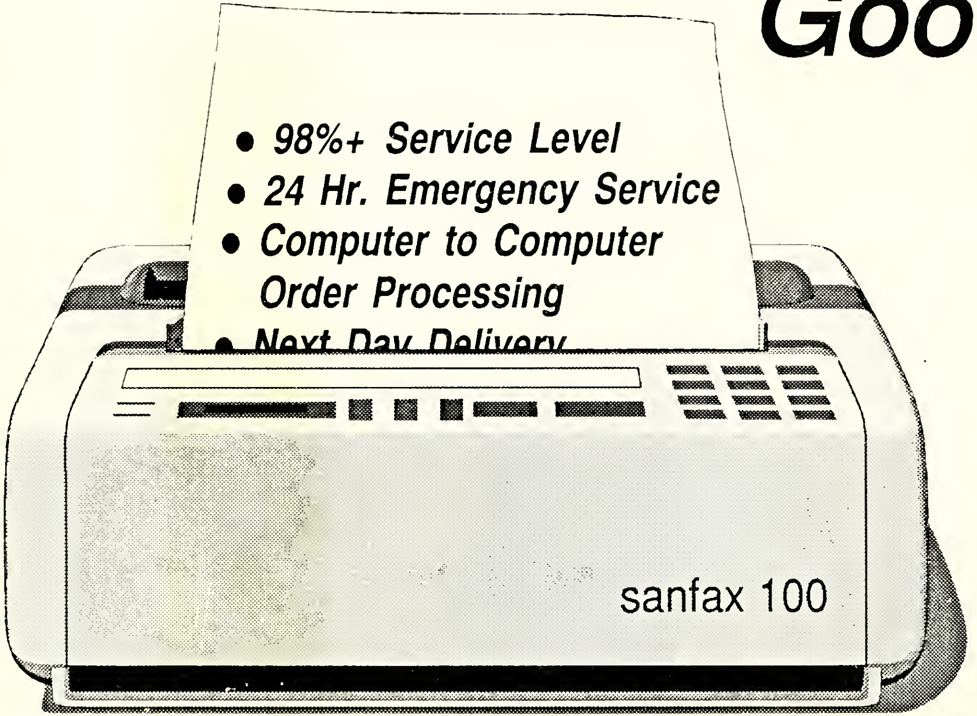

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Important figures in diabetes care

7

Diabetes is the **No. 7** cause of death in the US[1]

1

Diabetes is the **No. 1** cause of new blindness in persons aged 20-74[1]

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1. *Diabetes Surveillance, 1980-1987.* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

PHARMACISTS SPEAK OUT

NCPhA President Betty H. Dennis

During the past several months, there has been increased grassroots political activity by North Carolina pharmacists, especially those in independent pharmacy practice. The primary issue that heightened awareness for the need for this activity was a reduced reimbursement plan for medication purchases by state employees. Although pharmacies were not required to sign any contracts for this particular plan and the reduced reimbursement affected primarily the state employee, the announcements received by state employees suggested that pharmacies routinely sell medications at AWP - 10% (no fee) and the state employee should be able to "shop around" and find a pharmacy that sells at this price. As your President, and a state employee, I found these mailings to be very complicated and misleading. I also believe that state employees were given unrealistic expectations about general retail pricing of medications.

Your Association, as well as many legislators, had the understanding that the law passed by the General Assembly last year related to this new plan provided for reimbursement to the employee based on AWP-10% plus a fee. The exact wording of the statute states: The covered amount for prescriptions is the Average Wholesale Price of the drug plus a dispensing fee to be determined by the plan administrator. The fee, according to those legislators on the committee, was expected to be the same as the Medicaid fee. The administrator set the fee at zero.

Major legislative accomplishments come through individual pharmacists getting to know their legislators....

It was not until early in the first of the year when the state announced the specifics of the plan that a "Legislative Alert" was mailed to all NCPhA members describing the fact that the reimbursement guidelines were established and did not include any professional fee. NCPhA officers and members met in Raleigh with Mr. David Devries, the Administrator of the State Health Plan, to discuss concerns about the plan and offer alternative guidelines. Due to a State Attorney General's ruling that Mr. Devries must implement the plan by April 1, no changes were made at that time. Meetings were also held with House Speaker Dan Blue, Senator J.K. Sherron and Representative Martin Nesbitt to discuss the impact on state employees and pharmacies with the implementation of this plan. We stressed that many state employees could not drive long distances to find a pharmacy that met the expectations of the State Plan. Reduced reimbursement for outpatient medications could lead to decreased compliance and ultimately increased costs due to increased doctor and hospital visits. The concept of "shopping around" may be wise for certain types of purchases but health care is often compromised by using many different providers for routine services.

Betty H. Dennis, President

The North Carolina State Employees Association has 56,000 members and initially was supportive of the State Health Plan because of suggestions that it would lead to lower prescription prices for state employees. Their executive director became supportive of the need to alter the reimbursement plan after discussions with pharmacists. State employees would be penalized to a greater degree than initially realized. All parties recognize the budget limitations of the State and are willing to work toward a more reasonable plan that does not put the "blame" for reduced reimbursement on pharmacies.

What is your Association doing about all of this? Letters have been written to legislators and meetings have been held. Resolutions will be presented and discussed at our State Convention in Pinehurst related to the need for increased political activity. An Academy of Independent Pharmacy has been formed by your Executive Committee to work with the pharmacists involved in this grassroots political activity on this issue and others. It is expected that the General Assembly will modify the reimbursement plan during the short 1992 budget session.

The good news about this recent problem is that pharmacists have realized the importance of increased political activity. Major legislative accomplishments come through individual pharmacists getting to know their legislators and expressing views on issues related to our profession and health care.

Thanks to all of the pharmacists, especially members, who took time from their busy schedules to SPEAK OUT and become visible. Legislators have stated that they don't routinely hear much from pharmacists. They have in the past few months. Let's renew our commitment to be a more visible profession with greater political awareness and activity. We can make a difference! Let's do it!

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LETTER, FROM ALASKA

March 1992

I sit by my fireplace-wool sweater, ragg socks, polypropylene and peer out the window. The snow continues to form a thick blanket over my car...it's funny, same thing happened three days after my arrival in October and hasn't stopped since then. Being blessed with more than 100 inches of snow this season, you quickly adjust. Earlier today, I talked to my parents, Joe and Barbara Greeson, in Thomasville. It's rather warm in the Chair City, warm enough for shorts and warm enough to get sunburned. Occasionally I become a little homesick, like today, and treat myself to some "pseudo-Carolinian" atmosphere: thermostat to 85 degrees, shorts, grits, and an ACC basketball video. Brief tranquility, I guess.

Though I miss North Carolina, there are many things that Alaska offers which can seldom be found or discovered elsewhere: the cross-country skiing in which you often find yourself sharing the trails with moose, snow shoe softball, the Northern Lights, Mt. McKinley and hundreds of bald eagles, grizzlies, etc. All in all, it's truly the Last Frontier.

I am employed by a large chain drug store/grocery store named Carr-Gottstein. There are only a handful of independents-specializing in compounding and/or medical supplies. The remainder of pharmacies belong to this "grocery" type environment. Perhaps it is too expensive for the independents here and most likely, it has been difficult for them to compete with these larger chains. With a population of roughly 250,000, Anchorage also supports 3 large hospitals including the Public Health Service's Alaska Native Medical Center (with former North Carolinians Emil Cekada and Jim Rogers).

My attraction to Alaska stemmed from an externship with the Public Health Service after my graduation in 1990. The experience left a beautiful mark upon my life: the hospital pharmacy staff and students, the Natives of Alaska—listening to polar bear tales from a 72 year-old (Eskimo) lady from Barrow, attending a tribal Pow-Wow/Pot-Lache, working for the hospitals in Kotzebue (approximately 30 miles north of the Arctic Circle) and Bethel (close to 400 miles west of Anchorage and across the water from Russia). With this came a closer understanding of the lives of the natives—and more importantly, of other human beings.

Unfortunately it is my impression that many Alaskans are alcoholics and substance abusers. It didn't take long in my retail setting to discover the numerous customers who abuse controlled substances. Number one on my list involves a lady I have met who goes by two different names. Under both names she has also listed her children; let's see, there's Carolyn, Carrie, Debbie...Macy, Mary, Matthew—a total of 13 names have been tracked! Coincidently, each profile contains prescriptions solely for Phenergan with Codeine. Calling the physicians has either brought a halt or cancellation of their prescriptions, or a change to Tessalon. Interestingly, we've returned all of the Tessalon Rxs back to stock.

Another area of some difficulty has been with the fax machine. It is legal to fax prescriptions, which has helped to cut down on time spent on the phone; however, problems have arisen. The ease of the fax has attracted many forgeries and the majority, if not all, have been linked to office personnel. Only the main office at Carrs has the ability and authority to give out the fax numbers. So although efforts are made to minimize the practice, forgeries will always be a problem our profession will have to confront.

My schedule consists of 12-hour days, Tuesday, Friday, Saturday and Sunday one week, and Monday, Wednesday and Thursday the next. Summer will bring a week on/week off schedule. Since my arrival, I have missed only one day of work. This occurred last week when I took off to do some down-hill skiing in Alyeska (a small community approximately 40 miles from Anchorage). My four hour road trip turned into a twenty-four hour vacation when I learned that there had been 3 avalanches between Anchorage and me. A deep depression overwhelmed me by the mere thought of having to ski instead of work...it took a nanosecond to snap out of it!

My boss and partner is a gentleman by the name of Frank Pratt. He and his wife, Verna, will be publishing their second book on Alaskan wildflowers. Most Alaskans, like Frank and Verna, truly enjoy the outdoors and life. These Alaskans are quite interesting people just like many in the Tar Heel State. Often times I will step out from behind the counter just to get a close-up view of a patient's skin fur boots, coats and hats. The hats are truly spectacular. Many times the animal heads are left on the top, the legs form ear-muffs, and the tails accent the back. If you'd like to purchase such an item, expect to pay a minimum of $300 with a wolverine or lynx hat at $500. They do, however, guarantee your head to stay warm.

Along the lines of finances, Alaska is a bit more expensive than N.C. A gallon of milk is $3.79, a gallon of regular unleaded gasoline is $1.05, a one-bedroom (unfurnished) apartment is approximately $500 a month, Nicoderm 21mg #14 is $55.40, Prozac 20mg #30 is $51.60, Tenormin 50 mg #30 is $25.20, a Proventil Inhaler is $20.76 and one dental visit with standard x-rays is $188. Alaska has no state tax, and there is a yearly dividend to all qualified residents (last year's was a little over $900 to each person).

Alaska is not for everyone, but it is a place I believe everyone should see. I practice my profession here as I would in North Carolina, with empathy, loyalty, and pride. Someday I will return to my home and hopefully I will carry with me a deeper understanding of pharmacy, of other human beings, and of life. But until then, its time to put another log on the fire...the thermostat is up, the grits are on the counter, and with a click of the remote, Dean and the Heels will be on TV.

Once again...North Carolina in Alaska.

Amy Greeson, UNC 1990

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JOINT STATEMENT ON THE ENTRY-LEVEL DOCTOR OF PHARMACY DEGREE

Adopted by
AMERICAN PHARMACEUTICAL ASSOCIATION
AMERICAN SOCIETY OF HOSPITAL PHARMACISTS
NARD: REPRESENTING INDEPENDENT RETAIL PHARMACY

PREAMBLE

The lingering issue of the entry-level degree for practicing pharmacists must be resolved expeditiously so that our profession can concentrate its full energies on serving the pharmaceutical care needs of the American people. In addressing this issue, the profession must ensure fairness and equity for its practitioners and students, which will result in the best possible service to the public.

Our organizations, representing practitioners of pharmacy, support a *new* Doctor of Pharmacy degree to be awarded for completion of pharmaceutical education designed to prepare a pharmacist for entry into practice. This degree will be distinct from many of the Pharm.D. degrees that currently exist in that it will focus on training for entry-level practice rather than specialty practice. The curriculum for this *new* Pharm.D. degree should be the focus of the accreditation standards for entry-level education that are set by the American Council on Pharmaceutical Education (ACPE).

We will apply our collective resources to the implementation of the principles outlined in this statement.

I. DEGREE TITLE

The entry-level degree for practice in the profession of pharmacy should be the Doctor of Pharmacy degree. The designation of the degree should be "Pharm.D."

II. THE *NEW* DOCTOR OF PHARMACY DEGREE

A. It is the responsibility of pharmaceutical education to provide a graduate prepared for immediate licensure and commencement of a career in *any* area of pharmacy practice. The focus of the curriculum should be to prepare pharmacists to deliver pharmaceutical care to patients. The entry-level pharmacy graduate should possess the knowledge, skills, and professional commitment:

- to be responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.
- to help people make the best use of medications.

B. Our organizations strongly encourage greater use by colleges of pharmacy of qualified active practitioners on their faculties and curriculum committees, as well as in other relevant programs and operations.

C. It is the responsibility of pharmacy practice to develop and provide appropriate postgraduate opportunities (e.g., mentoring, residencies, fellowships) to achieve full and continuing competence in the various areas of pharmacy practice.

D. Among the characteristics of the *new* Doctor of Pharmacy curriculum should be the following:

- Sufficient general education to prepare pharmacists to function as active and informed citizens and professionals.
- Instruction in basic, pharmaceutical, clinical, behavioral, and administrative sciences that serve as the basis for the provision of pharmaceutical care.
- Development, through instruction and practice, of the communication and interpersonal skills necessary for effective counseling and communication with all consumers of pharmaceutical care.
- Development of skills in the selection,

initiation, and management of drug therapy.

- Development of the problem-identification and problem-solving skills vital to contemporary pharmacy practice.
- Development of a personal commitment to the patient as the focus of professional practice.
- Development of an understanding of the social, ethical, professional, legal, and economic issues in health care.
- Development of an active learning process based on inquiry.
- Development of an attitude of lifelong learning and the ability to adapt to change.
- Development of professional pride and self esteem, which encourage active, responsible roles in health care.
- Encouragement of active involvement in and commitment to the development and delivery of pharmaceutical education.
- Provision of undergraduate practical experience, under the guidance of pharmacy practitioners, that is sufficient in quantity, quality, and diversity to permit immediate licensure upon graduation.

III. DEGREE EQUIVALENCE FOR CURRENT PRACTITIONERS

A. The issue of degree equivalence is of primary importance to practitioners, although it also has implications for those in pharmaceutical education and accreditation. The issue is one of professional equity, equal professional opportunity, and the avoidance of real or perceived professional or career barriers.

B. We strongly encourage colleges of pharmacy to develop a degree transfer process for current holders of the Bachelor of Science in Pharmacy degree. This should be done with the active support of ACPE.

C. Our organizations will develop an institute for the purpose of granting a *certificate of Pharm.D. equivalence* to current practitioners with the Bachelor of Science in Pharmacy degree.

1. The institute will offer this *certificate of Pharm.D. equivalence* for a defined period of time.
2. The institute will provide a variety of options to attain the *certificate of Pharm.D. equivalence* (e.g., self-evaluation with self-directed continuing education program; a defined, curriculum-based continuing education program or series).
3. The equivalency process will serve to establish comparability between the professional qualifications of Bachelor of Science in Pharmacy and *new* Doctor of Pharmacy degree recipients.
4. Our organizations will actively foster universal acceptance of this degree equivalency process.
5. Pursuit of the degree equivalency process will be kept strictly confidential.
6. A pharmacist's decision not to pursue or not to complete the degree equivalency process will have no effect on his or her state licensure.

The American Council on Pharmaceutical Education (ACPE) has announced its intention to establish accreditation standards based on a six-year Doctor of Pharmacy (Pharm.D.) program as the single entry level degree. This issue of *The Carolina Journal of Pharmacy* features comments, statements and positions from various national pharmacy associations and pharmacy leaders about the proposal to mandate a single entry degree for pharmacy, the Doctor of Pharmacy degree. It is a matter of importance to students, faculty and pharmacists. There are as many opinions as persons to ask. You have heard and read much about this and we ask you to carefully read the opinions expressed in this *Journal*. NCPhA will take a position on the Pharm.D. issue after evaluating the survey which will closely follow this magazine. Your opinions will determine the NCPhA official position so be on the lookout for the survey. Complete the survey as instructed and return it by the requested date.

Al Mebane, Executive Director

PHARMACY EDUCATION IS NOT ON THE WRONG TRACK

By Leonard J. DeMino, R.Ph.
Vice President, Pharmacy and Health Affairs
National Association of Chain Drug Stores

The future of pharmacy education is at a critical crossroads. At this juncture is a group advocating revolutionary changes in the future for pharmacy education. While far from a majority viewpoint of practitioners and educators, they claim pharmacy education is on the wrong track to meet future patient needs. Leaders of this movement advocate a single entry-level degree structure centered on a doctor of pharmacy (Pharm.D.) degree. They incorrectly promote a perception that there is a broad justification and support to embark on an unproven course.

A significantly large segment of the pharmacy education and practitioner community questions, indeed does not support, the proposal to mandate a six-year degree structure for entry into the profession. Those voicing their opposition to the Declaration of Intent by the American Council on Pharmaceutical Education (ACPE) to accredit only Pharm.D. programs for entrance into the profession are basing their opposition on factual analyses, marketplace realities and the lack of factual based evidence that a Pharm.D. program better prepares a pharmacist for community practice. Further, they cite the lack of any evidence which shows five-year B.S. pharmacists are not adequately prepared for practice.

Chain pharmacy believes, as do the vast majority in community practice, that enhanced patient interaction, improved medication use and enhancement of the role of pharmacists in the health care delivery system are important elements to the future of pharmacy practice. In fact, NACDS has supported the mission of pharmacy practice as helping patients make the best use of medication, including the responsibility for dispensing prescribed medications when indicated.

Chain pharmacy is not alone in its concerns over how the process to bring about change in pharmacy education is being implemented. Pharmacy practitioners, educators and employers across the nation strongly support continuation of a five-year generalist approach for entry into the pharmacy profession and as the first step in a logical progression to advanced studies as needed.

- A national survey by SRI International found 64% of community pharmacists surveyed disapprove of a mandatory Pharm.D. program.
- Employers of community pharmacists, in both independent and chain drug store settings generally do not distinguish in their hiring practices between 5-year B.S. graduates and Pharm.D. graduates.
- A survey of nearly 2,000 independent retail pharmacists' showed that over 60% believe the time required to complete the first professional degree should be 5 years.
- Nearly 60% of pharmacy school deans surveyed by SRI International do not support the requirement for an exclusive Pharm.D. program.
- A Gallup survey of full-time pharmacy school faculty determined that 63% feel the progression from a 5-year generalist degree to an advanced Pharm.D. degree as needed will best prepare pharmacists for various practice settings.

Chain pharmacy strongly supports a multiple-degree structure for pharmacy education which includes high-quality educational programs at both the baccalaureate and doctoral level. This structure provides schools and the profession with the best opportunity to meet the diverse spectrum of health care needs in pharmacy.

Community pharmacists and educators increasingly are voicing concerns and expressing opposition to a mandatory six-year entry level degree for pharmacy education. A brief sampling of recent developments across the country reveals that:

- In adopting an official position, the Ohio Pharmacists Association, which represents 3,500 pharmacists, stated in November, 1991 the OPA is "...in opposition to the concept of a doctor of pharmacy degree for all pharmacists. The membership has not been convinced of the societal needs for this degree program, and is extremely concerned about the practical consequences of such an action...The bottom line is that B.S. practitioners are serving the needs of society quite adequately."
- The Massachusetts Board of Pharmacy, in September 1991, went on record officially opposing the ACPE Declaration of Intent to accredit only six-year mandatory Pharm.D. degrees as the entry-level degree.
- Preliminary results of a survey of the Pharmacists' Association of Western New York (PAWNY) show that 77% of its membership does not support a joint proposal by APhA, ASHP and NARD for a single doctor of pharmacy entry-level degree.
- The Board of Regents of the American College of Clinical Pharmacy reaffirmed in February, 1992 its previous position that "high quality educational programs at both the baccalaureate and doctor of pharmacy levels are needed to produce pharmacists who can meet the entire spectrum of patients' pharmaceutical care needs."
- A survey of its members by the Utah Pharmaceutical Association, in November, 1991 showed that 97% of the respondents favored the B.S. degree as the entry-level degree in pharmacy.
- In Rhode Island, the state board of pharmacy has reached a consensus that B.S. trained pharmacists are adequately educated to practice their profession, and do not need the extensive training of Pharm.D. programs. The Rhode Island Board also officially opposes mandatory entry-level Pharm.D. programs to replace pharmacy's B.S. programs.
- At its 1990 annual meeting, the Michigan Society of Hospital Pharmacists surveyed its membership about entry-level programs for pharmacy. The results demonstrated that 74% of the respondents were opposed to the Pharm.D. as the only entry-level professional degree. A majority felt the multiple degree system should continue.

The opposition to a mandated six-year entry-level degree for pharmacy and elimination of the B.S. degree program is strong and growing. The examples cited above represent the sentiment of many practitioners and educators. They recognize that the pharmacy education issue must be viewed on a basis of facts and research and reflect commonly accepted viewpoints.

No realistic evaluation of a mandatory entry-level Pharm.D. program for pharmacy education would be complete without a thorough analysis of the impact such a change would have on future pharmacy manpower. The pharmacist supply issue is real. The present shortage of pharmacists and the projected need for increased pharmacist supply deserves legitimate discussion in terms of health care costs and the future practice of pharmacy.

A 1990 report to the American Association of Colleges of Pharmacy Council of Deans by Jordan Cohen (Kentucky) and Charles Rutledge (Purdue) showed that the projected impact of a mandatory Pharm.D. program would average a 33% decrease in class size. Further, an independent study by SRI International conservatively projected a 20-30% decrease in class size would result from implementation of a mandatory Pharm.D. degree.

Pharmacists in North Carolina, as well as elsewhere, should demand from those proposing revolutionary change in pharmacy education factual answers to critical issues. Each of these issues must be approached from the perspective of how proposed changes in pharmacy education will impact pharmacy's ability to meet present and future patient needs. A legitimate evaluation must consider, at a minimum, all of the following:

Patient Needs
Educational Resources
Other Health Care Providers
Drug Distribution and Control
Cost to Health Care System
Doctoral Standards
Educational Resources

Pharmacist Supply and Demand
Technicians and Their Role
Dispensing Automation
Pharmacy Practice Standards
Professional Judgment
Regulation
Economics
Consumer Attitudes
Marketplace Realities
Reciprocity
Degree Transfer
Degree Equivalence

Undoubtedly, there are many more pertinent concerns, in addition to these, that must be fully and adequately addressed. The effort to derail pharmacy education in America is not justified. The profession must insist that schools of pharmacy retain the right to decide what degree programs best meet the needs of the public in the state they serve.

(Editor's Note: Leonard J. DeMino served as a member of the Maryland State Board of Pharmacy for 15 years from 1976-1991. From 1972-1989 he was Vice President of Pharmacy for People's Drug Store overseeing 850 pharmacies in 15 states. Currently he is a member of the Board of Visitors for the School of Pharmacy at the University of North Carolina.)

DAVID R. WORK CHOSEN NABP'S 1992–1993 PRESIDENT ELECT

David R. Work, J.D., R.Ph., executive director of the NC Board of Pharmacy, was elected President Elect of the National Association of Boards of Pharmacy at the Association's Annual meeting in Salt Lake City.

Work will automatically assume the duties of president at the 1993 annual meeting of the Association. Following his year as president, he will serve one year as Chairman of the NABP Executive Committee.

Mr. Work was instrumental in the development of counseling techniques for patients who are functionally illiterate. He was largely responsible for the USP's pictogram labeling program, which assists in counseling patients through the use of easily understood graphic designs.

David R. Work

Before assuming the office of President Elect, Work was vice president of NABP. He has served on the Executive Committee for the past three years and is the liaison to the Federal Drug Law Examination Advisory Committee. He has also served two years as Executive Committee liaison to the NABP Committee on Pharmacy Practice and also as liaison to the Advisory Committee on Examinations. He was a member of the NABP Subcommittee to Revise the Model Pharmacy Practice Act. He is an adjunct professor at both the Campbell University School of Pharmacy and the University of North Carolina School of Pharmacy.

He is a 1961 graduate of the University of Iowa School of Pharmacy and received his Doctor of Jurisprudence degree from the Denver College of Law in 1968. He served on the legal staff of Blue Cross of Illinois in Chicago and was Director of Association Affairs of the National Association of Retail Druggists (now NARD) also in Chicago. He served on the faculty of the UNC School of Pharmacy as Associate Dean and was appointed to his present position in 1976.

ONE DEGREE, PHARM.D., IS RIGHT FOR TODAY

Marily H. Rhudy, Immediate Past President
American Pharmaceutical Association

All of us want the very best for our children and are willing to take extraordinary measures to see that they have the proper tools and guidance to succeed in a fast-paced, highly competitive culture. The profession of pharmacy owes its current and aspiring pharmacy students the same commitment to better opportunities. Even more than that though, pharmacy has made a covenant with it's patients to provide comprehensive pharmaceutical care.

In my opinion, **pharmacy education must progress to a single level**, doctor of pharmacy degree to accomplish both the commitment to new pharmacists as well as the covenant to our patients. There are many arguments supporting the all Pharm.D. degree, but the most compelling one, in the short run, is to provide ultimate flexibility to pharmacy graduates in choosing their practice sites. Knowing that the graduates will make several career changes within their professional life requires that we not impede their progress by short-sighted planning early in their education.

By continuing to support two degrees in pharmacy, we are perpetuating the class system of "clinical pharmacists" and "just pharmacists." It is not uncommon to read advertisements that say, "Pharm.D. only, need apply." I believe that pharmacy's new graduates should be qualified to apply for any position that they desire. Do all pharmacist's need a six year, clinically composed curriculum to practice in every setting today? Absolutely not. Will they need an educational experience that differs from my five year BS degree, to practice into the 21st century? Absolutely.

A second, long view and equally compelling argument for the Pharm.D. degree is the covenant between this profession and the patients who need us. This country is sorely lacking in medication use management in the ambulatory setting. When practice, academia and the public as a whole recognize (and reimburse for) the positive impact that pharmacists have on a patient's drug regimen, their overall health and the economics of their health care, the debate will be settled. And the smoke screen over manpower concerns will prove the detractors to be benevolent hypocrites. Today's bright young graduates will lead pharmacy to its rightful position of responsibility for the patient's optimal therapeutic success.

This country is sorely lacking in medication use management in the ambulatory setting

The American Pharmaceutical Association and other organizations conducted a study dating back to 1948 that called for the establishment of a six year Pharm.D. program. Surely 44 years is long enough to study. Vain posturing is delaying progress. Lady Macbeth said "Screw your courage to the sticking place..." Let's do the right thing for those we lead and those we serve.

ROB BIZZELL ATTENDS LEADERSHIP TRAINING CONFERENCE

W. Robert Bizzell, President Elect of the North Carolina Pharmaceutical Association, was among pharmacy leaders from 47 states and the District of Columbia who attended a Leadership Training Conference held recently in Kansas City, Missouri.

The two-day conference, sponsored by Marion Merrell Dow Inc., was designed to provide incoming presidents of state pharmacy associations with practical information and instruction in leadership/management techniques to help make their term of office as president a satisfying and productive experience.

THE PRICE OF A PHARM.D.

Christopher Rodowskas, Jr., Ph.D.
Editor, *Pharmacy Business*

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The January issue of *Pharmacy Business* contributed to the mounting discussion of a single Pharm.D. entry degree to pharmacy. The personal side of the issue for B.S. pharmacists is the impact of a new "better" degree on their career path. Although there is little evidence that established practitioners have much to lose as far as job security is concerned, it is worrisome to consider the implication for job advancement when all new graduates will hold the Pharm.D.

In the last issue we raised the question of what to do about earning a Pharm.D. when one already has a degree, a job, family and other financial responsibilities. We will proceed from where we left off. You are reminded that many have the urge to return to school, but very few are willing to pay the price in time, money, and change of lifestyle.

> *Do I want the Pharm.D. to secure or advance my career or do I wish to practice pharmacy at a more clinical level?*

Before discussing the economic and academic issues, let's do some self-inspection. Do I want the Pharm.D. to secure or advance my career or do I wish to practice pharmacy at a more clinical level? The latter may be the more ideal motive but the faculty role models you are most likely to be aware of are limited in number. As there are more Pharm.D.s, they are more likely to be doing what we might define as the "general practice" of pharmacy. For the most part, the job opportunities will remain in the community setting. Most believe there is much room for professional role expansion in the drugstore but the space has to be created. It is not there waiting for you. We must also remember that the clinical roles now filled by many Pharm.D.s require the degree plus a residency and a fellowship.

Time and Money

After soul searching about your motives, and if your interest remains high, the next questions deal with time and money. There are Pharm.D. programs which may be completed in one calendar year, but most require at least two academic years, four semesters, or about 60 weeks in school. The start to finish should take about 20 months, given vacations and breaks.

Since students are not in school all of the time, it is possible to earn extra dollars as a licensed pharmacist. It is not realistic to believe you will have a great deal of time for outside work, an estimate of the equivalent of four months of fulltime work over the 20 months would be the maximum. At $20 per hour, 40 hours per week, for 24 weeks, a Pharm.D. student could theoretically earn $19,200 over the course of study or $9,600 per year.

On the outflow side, let us assume the annual loss of fulltime earnings at $44,000 plus $5,000 in fringe benefits. If the student must relocate, there will be extra moving and travel costs and the likely loss of some of the earning potential of the spouse. You must also adapt to a new standard student level living which, with frugality, may allow you to sustain yourself at $1,000 per month for household expenses. This is a very low estimate and will vary with your other personal responsibilities.

There are wide variations among colleges in tuition costs, but it is not unusual for Pharm.D. students to pay higher fees than their B.S. counterparts. For a rough estimate, we will use $6,000 per year to compute tuition and academic fees. If you have been away from school for a while, you will be amazed at the price of textbooks. In addition to required texts, the Pharm.D. students must begin investing in a substantial professional library. One can also anticipate the need for a personal computer. We will estimate the cost of books and educational supplies at $2,500 for the full program. Professional travel is not an expense for undergraduates, but the Pharm.D. students often expect to attend the ASHP Midyear Clinical Meeting and regional gatherings. We estimate professional travel expenses at $2,000.

A summary of costs for a practicing pharmacist returning to school under the assumptions described are found in Table 1.

If we wish to look at the economic cost/benefits of the $115,000 expenditure, over a 30-year post-Pharm.D. career life, the cost is $3,850 per year. Considering the time value of money, it would be reasonable to apply a multiple of 2, 2.5 or 3. The annual costs then become $7,700, $9,625 or $11,550. To put those into perspective,the $44,000 salary would become $88,000, $110,000 or $132,000. These translate into 8.8 percent Pharm.D. salary over B.S. salary to reach a 1.0 cost/benefits ratio with benefits measured solely in income.

We have not fully considered the human psychological side of the investment. It is difficult to quantify, but there is a cost to geographical separation, emotional strains created by a return to the academic grind and the leaving of a relatively affluent lifestyle. These apply to both the student and the family.

Preparing Yourself to Return to School

If you have done your own arithmetic, and still wish to pursue the Pharm.D., you must recognize that the longer you wait the more costly it will become. If you are unwilling to take the plunge immediately, you may wish to begin to prepare yourself for a return to academic rigors. The amount of preadmission preparation will probably depend on how confident you are about your ability to return to fulltime study. Your confidence level will most likely depend upon past performance in school and the length of time you have been away from the classroom.

Table 1

Estimated Costs Associated with a Practicing Pharmacist Returning to School to earn the Pharm.D. Degree

Lost Income	
Lost salary	$88,000
Lost fringe benefits	10,000
Total lost	$98,000
Plus part time earnings	19,200
Net income loss	$78,800
Expenses	
Tuition and fees	$12,000
Household	20,000
Professional travel	2,000
Books, educational materials	2,500
Total expenses	$36,500
Total of net lost income and expenses	$115,500

For those who have been out of school for some time, it is especially important to examine how the curriculum has changed, what prerequisites exist that were simply not there when you were in undergraduate pharmacy school, and if there are deficiencies, how can they be remedied as quickly and painlessly as possible. Your own practice experience can compensate for the lengthier externship programs. A bigger concern may be the new basic knowledge needed to compete academically. There is a whole new therapeutic, clinically oriented approach to pharmacology instruction and, while good old *Goodman and Gilman* is still essential, there is more to the story. Among the basic sciences, some older graduates have not yet dealt fully with the revolution in biochemistry and the increased emphasis on immunology. One must also develop a working knowledge of pharmacokinetics and both kinetics and therapeutics require a knowledge of calculus and applied statistics.

The calculus and statistics can usually be found as introductory courses at a low cost community college. The recommendation to follow these interests by actually enrolling in courses allows you to accomplish several objectives. First, a community college and an introductory course approach is a fairly painless return to formal study. Next, for many learners, it is difficult to master quantitative techniques without being subject to the supervised rigors of problem solving. Finally, by testing the waters in a convenient, low cost situation, you have an easy test of your own readiness to return to school for a doctoral program.

·In selecting calculus and statistics courses, look for applied offerings. You want practical example oriented instruction to apply in clinical practice. Quite often, you will find specialized introductory courses for the biological and/or social sciences, including business administration. These are preferable to the more theoretical courses designed for physical sciences and engineering majors.

With basic quantitative skills in hand, the aspiring Pharm.D. student may wish to fill the "clinical gap" that exists in pre-1990 pharmacy education. To find useful materials, I met individually with Drs. Edmund J. Hengesth and Schott A. Swigart, both of Ferris State University. Dr. Hengesh is a pharmacist with a Ph.D. in biochemistry and Dr. Swigart, a Pharm.D. who heads the pharmacy practice department. I explained that I was looking for books or other resources which had a teaching rather than a reference orientation; in other words, materials that could be used for self instruction.

Dr. Hengesh suggested *Harper's Review of Biochemistry* in its latest revision. The book is from the Lange Medical Books series which offers a good selection of up-to-date reviews. There are also offerings in *Basic and Clinical Pharmacology, Pharmacology: A Review, Basic and Clinical Immunology* and others. They are available by mail on 30-day approval from Appleton & Lange, 25 Van Zant St., E., Norwalk, CT 06855.

Since pharmacy represents a narrower field of interest than biochemistry, Dr. Swigart suggested more traditional texts. He noted that these were self instructional and made only reasonable assumptions of prerequisite knowledge. His suggestions were:

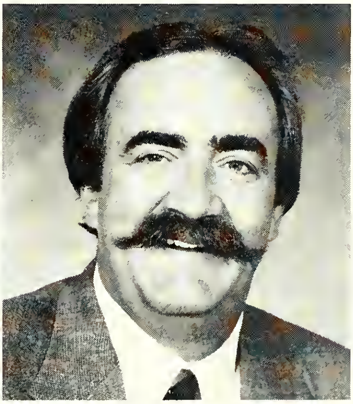
Michael E. Winter, *Basic Clinical Pharmacokinetics*, 2nd edition, Applied Therapeutics, Inc., 1988.

Joseph T. DiPiro, et al, *Pharmacotherapy: A Pathophysiological Approach*, Elsevier, 1989.

This guide may be helpful, but it does not replace doing your own homework. The decision to return to school will be one of the most important of your life. Research the question carefully; speak with those having the types of jobs you aspire to; visit the programs and speak with students and faculty. Weigh your options and their costs and benefits with the ultimate precision.

Good luck!

MCALLISTER ELECTED TO JCAHO COMMITTEE CHAIR



Jim McAllister, immediate past president of the American Society of Hospital Pharmacists (ASHP) has been elected chairman of the Home Care Accreditation Program Professional and Technical Advisory Committee of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO.) The group is charged with recommending improvements to the Joint Commission's home-care survey and accreditation process. McAllister serves as director of pharmacy at Duke University Medical Center.

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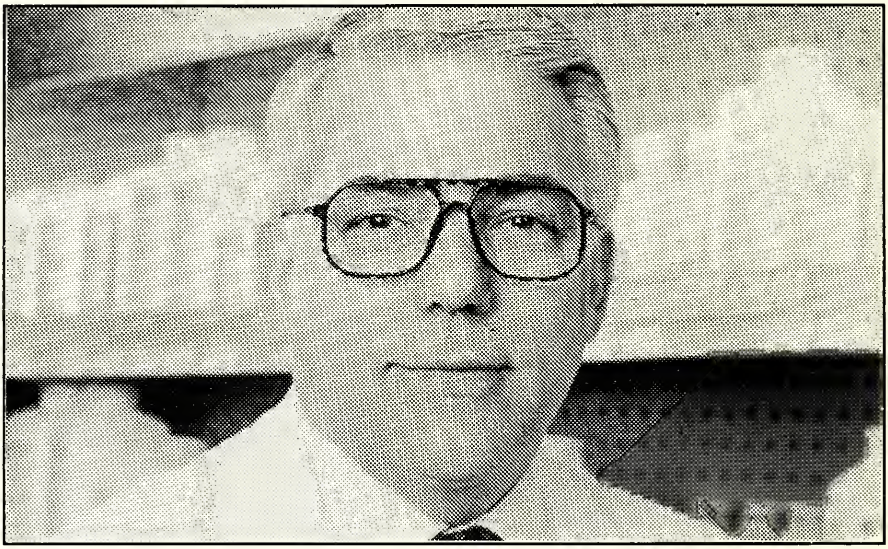

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BEYOND THE GREAT PHARMACY DEGREE DEBATE

Editorial by Raymond A. Gosselin, Pharmacist
Editor-In-Chief, *Pharmacy Times*

Reprinted with kind permission of the editor, from Pharmacy Times. *April, 1992*

What started out for most of us as reasonable discussions about the long-term pluses and minuses of a B.S and/or Pharm.D. *option* has escalated to a B.S. *versus* Pharm.D. *battle*. It has become an emotional issue over process and turf leading to polarization. All this obscures a very fundamental point: The issue is whether the profession can survive a major incremental cost in its educational component when cost controls are stifling pharmacy practice. It is not an issue of title, status or gaining new professional high ground. To illustrate, we recently heard that a respected national association board member said there was no need for all the fuss about an all-Pharm.D. program for he recalled the "easy" transitions from the three-year Ph.G. to the four-year B.S. and then to the five-year B.S. as the prerequisite for licensure.

These, however, occurred before *cost containment* made its way into the lexicon of pharmaceutical and health care practice, and long before pharmacy service costs attained the visibility they have today. The harsh reality of the 1990s is that health care has entered an era where absolute control of costs has emerged as a basic and structural component of the health care paradigm. This, more than anything else, will govern the future direction of our profession. How to contain costs will be as fundamental a tenet as any law of pharmacodynamics.

Pharmacy needs to find *innovative* ways to make itself as cost-effective as it can possibly be for the benefit of society while protecting the economic viability of its practitioners. That means finding ways to educate and train pharmacists to do all the good things expected of them by even the most zealous proponents of pharmaceutical care, but in the most cost-effective way. That requires being time-efficient both in education and in practice. Adding another expensive year to the curriculum should not be viewed as the *only* solution for preparing people to meet new challenges.

Proponents of a universal six-year program argue that overall cost-effectiveness might be gained in health care sometime in the future, assuming that all other variables remain constant, a condition only found in research laboratories. The idea is a bit hypothetical for it doesn't take into account reactions and countermoves by other health professions, which are also under the cost-containment gun and seeking new and expanded roles. Nor does it take into account the reality that cost-containment decisions are made on the basis of short-term expedience. From our academic experience of over 25 years, we know that there are many innovative (maverick?) academicians who, if challenged, could develop new methods of preparing students to do it all in *less* time.

First, there has to be an "unlearning curve" to dispel the idea that adding time is the only approach to enhanced education. This dismays academic traditionalists who are comfortable with the concept of addition, but uneasy with subtraction. Further, creative faculty, coupled with the active input of pragmatic practitioners, can help unlearn the ways of contemporary continuing education to truly keep pace with constantly accelerating change in therapeutics and practice methods. By the time students reach their first practice site, even the most current material they learned as undergraduates is outdated. Students should be educated to understand, accept, and cope with change. They need to know how the environment in which they will practice really operates and how to efficiently access and use information. Postgraduate continuing education should provide specific new knowledge on a real-time basis. We recognize the genuine problems of therapeutic misadventures, and the great cost-effective and humane good that can come from their avoidance by proper pharmacist intervention, but we think pharmacists could perform this critical task without increased undergraduate learning *time.* It could be done with an innovative revision of program content and creative use of new technologies and teaching methods.

It is in the best interests of society and the profession that we preserve the highly accessible and efficient community pharmacy, irrespective of its ownership. Who owns a pharmacy today has little to do with actual operational philosophy. Rather, business philosophy is dictated by consumer demand and *they* have created and sustained the great American Drugstore. Retail pharmacies are, and must remain, the principal providers of needed Rx and OTC drug products to the growing ambulatory population in need. And they should be the place for obtaining knowledge and information about proper drug use. Pharmacists need to exercise professional judgment on behalf of each person they deal with, taking into consideration the highly diverse nature of human beings whose needs for information, counseling, and the efficient use of time are varied. The wholesale and retail drug distribution system in America is already highly efficient, and each day it applies new technology to more speedily and cost-effectively bring products into every community. In an era of inescapable postal rate increases, mail order prescription services will be hard put to remain a viable economic alternative to retail distribution. On the other hand, dispensing physicians using drug information and interaction software could pose an economic threat to "super pharmacists."

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In an era of entrenched cost-containment on prescription drugs, the ability to sustain and manage a full "front store" component needs to be relearned to provide the economic base for the provision of this vital community service. Pharmacy could "shoot itself in the foot" despite all good intentions by making the pharmacist visibly the most expensive component in the financial transaction of acquiring a prescription drug.

Under cost-containment, arguments for a theoretical greater long-term good give way to the expedience of immediate cost-cutting. Look to recent and inadequate dispensing allowance, the discounting of AWP, limited refills, large quantities dispensed per Rx, mandated interchange, and the like. An all-Pharm.D. six-year program in *all* schools would too easily give focus to the next target of opportunity for cost-containment, the "super pharmacists." Radical cost-containment schemes would be proposed, e.g., a cheap, nonrobotic (robots can't do DUR), community-based, "down-sized" pharmacist licensed to dispense and counsel "by the book," and do utilization review for *cost-containment purposes only.* The more esoteric monitoring and counseling services would be assigned to other health team members eager to show administrators their worth and cost-efficiency capacities. These ideas would have high appeal to government (remember, the VA and FTC support mail order) and private payors.

A conscious decision not to decide is in and of itself a proper decision.

Our view is that while the current two-degree system bothers some, there are no signs of widespread dissatisfaction at the grass roots level, nor of imminent disaster because there is an *option.* Any person who aspires to a career in pharmacy is free to exercise his or her own personal choice and there are many programs from which to select. There are no signs that the consuming public is demanding that pharmacists declare their academic credentials *before* a patient will hand over the prescription to be filled, or before a patient will ask a question or seek advice. The 10,000 or more pharmacists who have earned a six-or seven-year "clinical" Pharm.D. degree and all those in the academic pipeline do not presently need to be concerned with having to compete with a new "hybrid" doctorate. There are tens of thousands of pharmacists who practice proudly in America's retail establishments. These are uniquely qualified and dedicated individuals, the majority of whom are where they want to be, doing exactly what they want to do in life. They have a talent and an attitude that breeds economic and professional success. We do not need to preach change to them; they live with it constantly.

We tip our hats to those men and women who every day greet the great American consumer in the dynamic and challenging arena of the marketplace. They deal with the full spectrum of human personality differences, the range of economic status, and the highly diverse individual knowledge levels and needs. Not everyone can do it, and not everyone should. Alternatives are there for those pharmacists who prefer to choose a different environment.

Some elitists in the profession look down on that which offends their personal criteria for "proper" professional practice. They would impose *their* views on all others and look to the regimentation that one and only one educational approach would dictate.

The key factors in the degree issue are time and choice. Time is money and costs are measured in terms of money. Before we take a precipitous step that could hobble the profession in an era of merciless cost-containment, let's drop the divisive B.S. *versus* Pharm.D. confrontation engendered by the imposition of an arbitrary process and timetable for a decision. A conscious decision *not* to decide is in and of itself a proper decision. The B.S. and/or Pharm.D. option offers the best hope for the profession for the forseeable future.

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You're traveling on business or vacation. You're eating the typical high-fat, high-cholesterol foods. And you're not exercising.

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With a little savvy, you can travel in style, enjoy local cuisine, and still keep a healthy lifestyle.

When you choose your menu - whether at home or on the road - follow the American Heart Association's dietary guidelines. They're for healthy people trying to prevent heart disease.

The AHA suggests breaking down your diet into a little more than half of the calories from carbohydrates, a third or less from fat and the rest from protein. Limit cholesterol intake to less than 300 milligrams per day, and keep sodium intake to 3,000 milligrams (about a teaspoon of salt) or less per day. If you drink alcohol, limit your daily intake to no more than one or two ounces. An ounce of ethanol (pure alcohol) is contained in 2 ounces of 100-proof whiskey, 8 ounces of wine, or 24 ounces of beer. The AHA also suggests maintaining your ideal weight and eating a variety of foods.

It's a matter of choices. Choose margarine instead of butter. Choose fish and poultry more often than red meats, and lean red meats more often than fatty ones. Choose low-fat dairy products such as skim and 1 percent milk, low-fat yogurt and low-fat cheese.

Here are some "Rules of the Road" on how to stay fit and healthy:

1. When flying, get up and move around. It improves blood circulation and could prevent a blood clot in your legs.
2. Order you airline meals in advance. Most major air carriers offer special low-fat, low-cholesterol meals.
3. While on a flight, drink mainly non-alcoholic drinks, and go easy on the alcohol. Because you may get dehydrated, it's good to drink liquids every hour. This also will force you to get up once in a while.
4. Choose restaurants with healthful alternatives to rich foods and sauces. Many ethnic foods such as Oriental or Mediterranean offer good taste with relatively little saturated fat and cholesterol compared to what you'll find in haute cuisine.
5. Choose a hotel with a good exercise facility. Then use it every day if only for a couple of laps around the pool or indoor track.
6. Walk wherever possible: up stairs, sightseeing, shopping, to a restaurant or meeting. The exercise you'll get makes a difference in how you feel. You also won't gain weight when you balance exercise with food intake.

Bon voyage and bon appetit!

HOPE IN THE SOVIET UNION

by LeRoy D. Werley Jr.

The Soviet Union is the world's largest country, occupying 1/6 of the earth's land mass and spanning 11 time zones. It is roughly 2 1/2 times larger than the USA. Until recently, the administrative subdivisions of the government were 15 Union Republics and 20 Autonomous Republics (administrative divisions within the Union Republics), based on nationality, giving political recognition to important minority ethnic groups. Russian is the official language but each republic has its own language corresponding to the major ethnic group within the republic. In general, there are about 130 officially recognized languages in the Soviet Union. The Russian language uses a cyrillic alphabet, as do about 70 other languages in the country. However, the Baltic languages (Latvian, Lithuanian and Estonian) use a Latin (Roman) alphabet, similar to the one for English. Other languages such as Armenian and Georgian have unique alphabets. English is popular in the schools and many youth and well educated have a basic knowledge.[1]

The Soviet Union has about 60 million square kilometers (2.3 million square miles) of arable land and pasture. Much of this is poor by western standards, however, so that sown crops occupy only 10% of the total agricultural land. There are about 28,000 collective farms (average area is 75 sq. miles). The state farms operate as "agricultural factories" on which farm workers are paid wages. Workers and peasants on both types of farms are permitted the use of small, personal "private" plots. These small private plots typically produce 33% of the country's meat, milk, eggs, and vegetables, and 66% of its potatoes. This small private sector depends heavily on state and collective feed supplies for its livestock. In general, the Soviet economy is in the throes of transition. The leadership is seeking to implement a more decentralized and flexible new economic mechanism to promote efficiency, raise living standards and to restore rapid economic growth.[2]

The Soviet people are generally concerned about their health, however since the early 70's the state of the nation's health has declined. Infant mortality has risen, cardiovascular disease and alcoholism are epidemic, and male life expectancy has declined. These health indicators probably reflect a deterioration of general economic conditions. Most people get care in hospitals and clinics operated and funded by the Ministry of Health, a system of free care that includes 94% of all health care facilities. A parallel "closed" system is maintained by certain elite government ministries and large factories. This closed system is considered to be of higher quality than the public one and draws a disproportionate share of health funding. Also, contrary to its design, Soviet health care is not really free. Patients treated in the public system are often required to pay doctors and nurses under the table to assure that medication is administered or that an operation is performed.[3] In addition, throughout the Soviet Union there are major shortages of basic medications, medical supplies, equipment, nurses and para-professional personnel. These critical health needs are currently being addressed with the resources and expertise of Project HOPE in the West.

It is noteworthy to point out that HOPE's involvement in the Soviet Union was the result of separate and unrelated urgencies, for example:

*1986-Nuclear accident at Chernobyl, creating a desperate need for anti-cancer medication and other pharmaceuticals.

*1988-Earthquake in the Republic of Armenia, which killed and crippled thousands and acutely strained local resources.

*1989-Train derailment and explosion in Ural mountain which left hundreds of severely burned passengers in need of treatment and rehabilitation.

Project HOPE's response in each case focused on short-term humanitarian efforts.

Teams of American specialists were assembled and dispatched to treat disasters. From those initiatives, an extensive and long term presence has been established. Good relations between Project HOPE and the health leaders of the Soviet Union have been intensely solidified. [4]

On December 12, 1990, President George Bush announced a Public-Private Presidential Initiative to provide urgently needed pharmaceuticals and basic medical supplies to the Soviet Union. Project HOPE was selected to serve as the lead agency to assist the Soviet Union with the emergency shipment of medical supplies and pharmaceuticals. The first Soviet Republics to receive assistance under the Initiative were Estonia, Latvia, Lithuania and Ukraine. In February of this year an Advance Team visited the capital cities of each republic, meeting with the Ministers of Health and their staff, with medical and civic leaders, and local private voluntary organizations. Selected sites were visited to determine whether each could securely store, distribute, and effectively utilize contributed supplies—based on the appropriateness of the population served, project goals and levels of medical sophistication. [4]

The Advance team that I was assigned to was programmed to visit Central Asia, and my responsibilities were to:

1. Provide pharmaceutical technical advice and expertise to the Advance team.
2. Meet with the Minister of Health personnel, pharmacists, local private organization volunteers, and physician personnel concerning drug selection and usage.
3. Discuss each republic's allocation of supplies and pharmaceuticals.
4. Review prepared lists of contributed supplies and the lists of supplies needed by each facility.
5. Submit trip reports and recommendations for handling medications and supplies.

Our HOPE team consisted of a Program Manager, Program Director in Moscow, two physicians, an interpreter, Economics Officer for the US Embassy and myself. We spent a few days in Moscow waiting for appropriate clearances to some of the remote areas we planned to visit. During this time our itinerary was changed 3 times to assure a meaningful visit. We left Moscow at 6 p.m. and arrived in Central Asia at 7 a.m. the next morning. During the next 8 days we were on a whirlwind tour of 2 Union Republics and 1 Autonomous Republic. We visited 12 different medical facilities in 9 cities and towns. Transportation was accomplished by plane (in one case a prop-driven bi-plane with struts, etc.), automobile, and by train (I have seen better).

We met with a Deputy Minister of Health and staff, civic leaders, local private organization volunteers, physicians, pharmacy staff and specialists regarding their needs in the pharmaceuticals, medical supplies and equipment. The facilities we visited were identified and controlled as Republic, Regional, District, City and speciality hospitals. These included Maternity, Child Care, Oncology, Pediatrics, Childrens Psyco-Neurological Hospital, Diagnostic and Rehabilitation Centers, Medical School and Institute and a large Central Warehouse. Each republic provided its own Ministry of Health staff including its own interpreter as they accompanied us on each site visit. I must say that they were excellent hosts during our entire trip.

Some of the equipment we were exposed to had Soviet labels and some of the facilities (dependent upon their administrative control) had the latest equipment and a good variety of pharmaceuticals and medical supplies. Generally, the facilities were outdated and poorly maintained. We were impressed with the professional staffs, many of whom were women. They all seemed dedicated to preserve the health care of the patient despite some of the most adverse conditions I have ever seen. In fact, one of the hospitals we visited in a remote area had no running water and was low in supplies. Some of the larger facilities had speech therapy and special education teachers, with ultra-sound, mechanical and surgical therapy. Dialysis departments were scarce and in many instances there was a real need for distillation and purification equipment. As we visited each site there was little doubt that there are major shortages in medications and medical supplies. They need to develop a sound materials management program involving policy manuals, security, storage, procurement and distribution of supplies.

I think our Advance Team was well prepared for the task at hand, in spite of the delays encountered in getting clearance for some of the remote areas. The facilities selected for this phase of the program were excellent choices and certainly well deserving of medical assistance. Shipment of goods including antibiotics, analgesics, dressings, sutures, bandages, iron supplements, vitamins, IV sets, catheters, etc. were scheduled for delivery to the selected sites within two weeks after our survey was completed. This is but one facet of the kinds of activities that HOPE is engaged in and it typifies the manner and the expediency in which assistance is provided.

[1] Culturgram for the 90's—USSR, Brigham Young University Public Services.

[2] U.S. State Department, Bureau of Public Affairs, Background Notes, USSR, 12/89

[3] Schultz, D.S., Rafferty, M.P., "Soviet Healthcare and Perestroika," *AJPH*, Feb 90, Vol 80, #2

[4] "Project HOPE in The Soviet Union," *Project Hope Manual*, May 1991.

Project HOPE is a People to People Health Foundation, Inc., an independent international non-profit Health Education Organization founded in 1958 by William B. Walsh, M.D., and whose son William B. Walsh, Jr., currently serves as President and Chief Executive Officer. Project HOPE currently conducts programs in 25 countries around the world.

(Editor's note: When Lee Werley wrote this article, there WAS a Soviet Union. We decided not to make any changes in the story because of recent political events.)

PHARMACY FACULTY NAMED FOR 1992 PMA PROGRAM

The Pharmaceutical Manufacturers Association (PMA) has announced the 1992 Pharmacy Faculty participants in the PMA Coordinated Program for Pharmacy Faculty. Forty five pharmacy school faculty members, including five deans, will attend one of the twenty five programs sponsored by PMA members this summer.

The faculty members will spend two weeks participating in conference sessions on site at PMA member firms. The sessions will be organized and conducted by the host company executives and will provide the faculty members with the opportunity to learn first-hand about industry procedures and practices relating to marketing, pharmacy administration research and development and quality control, among others.

Begun in 1976, this program has provided over five hundred faculty members with the opportunity to exchange ideas and participate in learning experiences with PMA members. More specific information can be obtained from the Public Relations Division of PMA.

Among the faculty members selected for this year's program and the companies to which they have been assigned are:

Howard M. Glazer, University of North Carolina – The Upjohn Company

Doyle M. Cummings, University of North Carolina – Merck

Stephen H. Fuller, Campbell University – Ortho Pharmaceutical Corporation

Louise Mallet, Campbell University – ICI Pharmaceuticals Group

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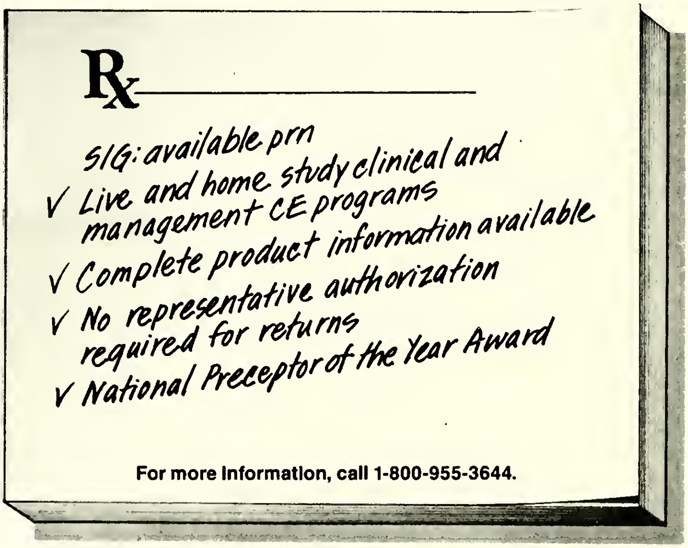

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DICKINSON'S PHARMACY

WHEN PHARMACISTS GET MAD

The world's most respected profession (yes, other countries now show the same rating as U.S. polls) may have earned that title by being slow to anger.

But that doesn't mean that as a group pharmacists never get angry—as every single member of the Florida state legislature found in December, when the state pharmacy association's hotline went into high gear.

The lawmakers got so heavily bombarded—executive director Rod Presnell estimates each got an average of about 80 calls—that they had to call the association to plead: "Please call your people off!"

What caused the fuss? The state awarded its government employees' drug program to a contractor (Consultec, Inc.) which in turn directed all prescriptions exclusively to the Eckerd chain.

By mid-January, when this column was written, Presnell was delighted with the response from his members, although it was still too close to the holidays to be able to tell what the state would do next.

A key element in the tremendous response was a powerful feature of the Florida hotline - pharmacists recruited patients to join their protest in direct contacts with legislators' offices.

Pharmacy wins when it brings patients to its cause. One pharmacist networking this cause among several hundred patients, energizing them to call or write, is exercising true political clout

This did four things. (1) It greatly increased the flow of calls into the legislators' offices. (2) It disabled any reflex the lawmakers may have harbored to belittle the complaints as "just a bunch of druggists sounding off." (3) It signaled an ominous warning that the controversy could spread without limit unless resolved quickly. (4) It consolidated the pharmacist–patient bond by establishing a political common cause grounded in patient care.

This is the wave of the future.

To the extent that pharmacists have been unsuccessful until now in persuading third-party programs, managed care companies, insurance plans, government agencies and lawmakers to preserve a fair business climate, Florida's experience suggests this may have been due to a lack of numbers.

The right numbers, that is. Two hundred pharmacists picketing the Blue Cross/Blue Shield office may be impressive on the evening news, but it's a drop in the bucket to a bustling, scurrying, worry-weary world.

Pharmacy wins when it brings patients to its cause. One pharmacist networking this cause among several hundred patients, energizing them to call or write, is exercising true political clout.

Multiply that by several hundred pharmacists, and you have a revolution in the making. Multiply it by several thousand pharmacists, and it's my prediction that no program's adverse policies will be able to withstand the impact.

But the weakest link in this entire power matrix is someone well known to you.

It's the owner of the face you see in the mirror each morning. If you don't reach out and start this, it may not get started.

So what does it take to get you to do this? In my experience, the pharmacist who suddenly finds that 20% of his or her clientele are going to be rolled over into a closed panel program or mail-order will be moved enough to do it.

I get a lot of calls from such pharmacists, but it's almost always too late at that point. When I call the offending program, I almost always find that they had not heard from the pharmacists until after the announcement—and then all they hear is abuse.

The abuse proves that pharmacists do get mad, but often when they do it's in a closed loop, when hardly anyone's listening.

The simple truth is that the pharmacists who lose this business have not been listening to local employers, or have not even made an effort to establish communications.

What's needed is a longer fuse, a slower burn. Start getting angry early. Plan a measured defense strategy. Pool your resources and your talents in a network with patients. Focus on quality of care, convenience, and patient rights. Reach out and touch someone.

It's the wave of the future.

This feature is written and presented by Jim Dickinson, on a grant from "Dickinson's Pharmacy–The Independent Voice," a professionally stimulating, practical eight-page monthly newsletter, available for an annual subscription fee of forty-five dollars ($45.00) from:

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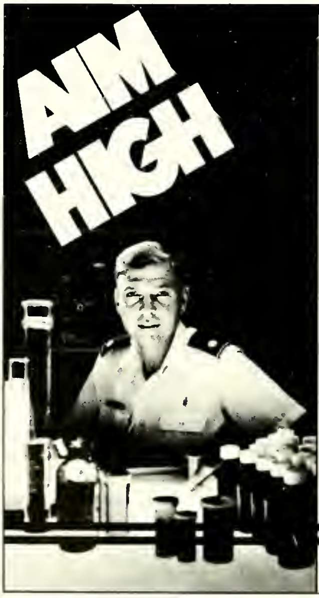

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CORRESPONDENCE COURSE

TREATMENT OF FEVER BLISTERS WITH OTC PRODUCTS: AN UPDATE

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Goals

The goals of this lesson are to:

1. review recent findings on the etiology and treatment of fever blisters; and
2. present the pharmacology and therapeutics of OTC remedies for treating fever blisters.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. differentiate between fever blisters and canker sores;
2. choose an appropriate OTC agent for treating fever blisters; and
3. know when to refer consumers to a medical specialist when self-treatment is not appropriate.

In January, 1990, the Food and Drug Administration (FDA) published proposed final rules to establish conditions under which OTC skin protectants and external analgesic drug products would be considered safe and effective for treating fever blisters. This culminated nearly a decade of intensive review of available information on these products following FDA's extensive system of: accepting reports from interested parties; publishing a Tentative Final Monograph (TFM); calling for additional comments on the TFM from industry, health care professionals, and consumers; and then, publishing the proposed rules.

If this category of drug product ingredients follows the norm to date, there will be another period for comments, followed by promulgation of the final rule which will define safe and effective ingredients for self-therapy of fever blisters, govern OTC labeling and manufacturer's claims, and regulate interstate commerce of external fever blister remedies. Oral agents which are claimed to be effective for treatment of fever blisters are still under review. The same is true for external remedies indicated for treatment of canker sores.

Differentiating Skin Protectants from External Analgesics

In the current TFM notice, the FDA defined drug products that provide a mechanical barrier to protect exposed skin surfaces from harmful or annoying stimuli, such as skin protectants. A discussion of specific ingredients considered safe and effective to self-treat fever blisters will follow later in this article. The overall group of skin protectants includes allantoin; aluminum hydroxide gel; calamine; cocoa butter; dimethicone; glycerin; kaolin; petrolatum; shark liver oil; white petrolatum; and zinc acetate, carbonate and oxide.

External analgesics are defined as ingredients that, when claimed to treat symptoms of fever blisters or cold sores, depress or stimulate cutaneous sensory receptors. External analgesics include local anesthetics such as benzocaine, butamben, dibucaine, dimethisoquin, dyclonine, lidocaine, pramoxine, and tetracaine, as well as certain alcohols and ketones such as benzyl alcohol, camphor, camphorated metacresol, juniper tar, menthol, phenol and resorcinol.

Oral agents (i.e., lactobacillus organisms and lysine) that are claimed to treat the symptoms of fever blisters were not addressed in the current TFM notice. They can continue to be promoted OTC until they are officially ruled on. If they are ultimately shown to be unsafe or ineffective, manufacturers will no longer be permitted to make therapeutic claims for them. If their efficacy is proven, however, manufacturers will then be permitted to promote them for this purpose.

Differentiating Fever Blisters from Canker Sores

Before discussing the treatment of fever blisters, it is appropriate to review canker sores and differentiate between the two. Since the terms fever blister and cold sore are synonymous, the designation fever blister will be used solely for the remainder of this article.

It is difficult to distinguish between fever blisters and canker sores (Table 1) because they are often confused for one another and referred to incorrectly. Nonetheless, each has distinguishing characteristics. Moreover, their

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causes and some treatments are totally different.

Canker sores (aphthous ulcers) are annoying, painful and recurrent ulcers that occur on the gums, lips, inner cheek, soft palate and tongue. From 20 to 50 percent of the population reportedly has experienced canker sores. They are not contagious, and invariably have an underlying cause that can be identified.

Fever blisters most commonly occur on the lips alone, or just inside the mouth. They, too, are irritating, painful and recurring. And they occur more commonly in cold weather.

Distinguishing between the two disorders with this terse information is difficult, but important to do so. As stated earlier, their treatment varies. Major factors believed to precipitate the disorders and means to control symptoms will be discussed as well as specific advice appropriate for patient counseling on fever blisters.

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Ulcers on the lips and inside the mouth appear fairly commonly. Not all lip or mouth lesions are canker sores or fever blisters. Many diseases cause them. For example, the lesions may signal an early symptom of several potentially fatal blood disorders, e.g., agranulocytosis. Several infective organisms also may incite them, such as the Coxsackie virus. Oral cancer normally appears initially as a mouth ulcer.

Oral cancer is of special concern because its causes are poorly understood. Symptoms include mouth ulcers that do not heal, persistent bleeding of tissues in or around the mouth, and swelling of the palate and other areas along with a feeling of numbness, pain and tingling.

In reality, there is no easy, consistently reliable method for distinguishing between fever blisters, canker sores and more serious oral disorders. If symptoms and lesion description match the information presented in this article, it may be a fever blister or a canker sore, but the symptoms can also be confusing. Bad breath, for example, is characteristic of fever blister formation, but it can also signal an oral bacterial or fungal infection. Whenever a mouth lesion fails to heal within two weeks or continues to bleed, professional consultation should be sought.

Canker sores vary in intensity from one person to another. The initial symptom usually consists of burning or tingling sensation in the area, leading to intense pain in the next 24 hours. At that time, an observable ulcer on the mucous membrane becomes evident.

Lesions are most common in the buccal and lip surfaces of the mouth. They range in size from 3 to 15 mm or more in diameter, and may coalesce to form single, large ulcers which are much more painful and require a longer healing period than the smaller lesions.

Canker sores are characteristically shallow and ovoid in shape, and have a slightly raised yellowish border which is surrounded by a bright red zone. Generally, within the next week the lesion becomes crusted with a yellowish opaque substance that consists of dried tissue fluids, bacteria and white blood cells. Pain persists for several days, although a sensation of slight pressure or irritation often remains for several additional days. Recurring lesions typically become less severe with time.

It is not known what causes canker sores. Since Streptococcus sanguis has been isolated from many canker sores, some authorities contend that this organism contributes at least partially to the occurrence and problems encountered with canker sores.

A cell-mediated localized autoimmune reaction may be partially responsible for canker sore development. It has been demonstrated that lymphocytes taken from sufferers of recurrent canker sores have much greater cytotoxic action on mucosal epithelial cells in laboratory experiments, than lymphocytes removed from persons without canker sores.

What is a Fever Blister?

Fever blisters, like canker sores, appear most frequently on the lips and adjoining areas of the mouth. They are also irritating, painful and recurring.

It is estimated that at least one-half of all Americans aged 20 to 40 years have had a fever blister. Most victims were infected before the age of five.

FDA defines them as vesicles that occur at the juncture of the mucous membrane and the skin of the lips or nose, and are caused by the Herpes simplex virus, type 1. Fever blisters are often referred to as herpes labialis. Another lesser used term is Herpesvirus hominis.

Unlike canker sores, fever blisters are highly contagious. They occur in a high proportion of individuals living under crowded conditions and heavily populated areas, and in persons of lower socioeconomic status. They are especially prevalent in areas of communal living, e.g., dormitories, prisons, nursing homes, etc. If a person residing in such surroundings develops a fever blister, they should take special care to avoid touching others while the active viral growth process is underway.

Fever blisters are characterized as yellow or white ulcers surrounded by a red halo. The margin of the gum in the immediate vicinity is swollen and red. As with canker sores, pain is intense. But unlike the former, fever blisters are accompanied by fever, increased salivation and mouth odor. Often times the glands in the neck are swollen, due to the body's response to overcome infection. While they are also caused by contact with an infected person, generally this is due to transmission via saliva, fluids from a sneeze, or a seemingly harmless kiss.

There are a number of other members of the herpes family. The herpes simplex, type 1 virus is usually, but not exclusively, limited to non-genital areas such as the mouth, nose and eyes. Herpes simplex virus, type 2, usually, but not exclusively, incites lesions in the genital area. Resulting lesions are referred to as herpes genitalis.

Fever blisters are subdivided as to whether they are occurring for the first time, or are recurrent to previous fever blister lesions.

Table 1

Factors Known to Activate Recurrent Herpes Infections

Factors Known to Activate Recurrent Herpes Infections
Fever
Chilling
Sunburn
Windburn
Menstruation
Upset stomach or GI disturbance
Emotional stress
Excitement
Minor infections
Dental treatment
Allergy to certain foods
Any disease that increases metabolism
Fatigue

Primary and Secondary Herpes Infections

When fever blisters appear for the first time on the lips or nose, they are referred to as primary lesions. If, by chance, the virus enters the circulation and causes generalized vesicular eruption on other areas of the skin, the infection is referred to as herpeticum eczema. The virus may also attack the eyes resulting in keratoconjunctivitis, a devastating infection which can lead to blindness if untreated. The virus can invade the central nervous system, leading to serious disease and permanent brain damage. This condition is referred to as meningoencephalitis.

Primary infections of the facial tissue are generally self-limiting and often mild enough that they do not cause irritating symptoms.

Table 2

Safe and Effective Ingredients for OTC Fever Blister Remedies

External Analgesics

Local anesthetics
- Benzocaine 5-20
- Butamben picrate 1%
- Dibucaine 0.25-1%
- Dimethisoquin HCI 0.3-0.5%
- Dyclonine HCI 0.5-1%
- Lidocaine 0.5-4%
- Lidocaine HCI 0.5-4%
- Pramoxine HCI 0.5-1%
- Tetracaine 1-2%
- Tetracaine HCI 1-2%

Alcohols and ketones
- Benzyl alcohol 10-33%
- Camphor 0.1-3%
- Camphor 3-10.8% with phenol 4.7%
- Camphor 3-10.8% with metacresol 1-3.6%
- Juniper tar 1-5%
- Menthol 0.1-1%
- Phenol 0.5-1.5%
- Phenol 4.7% with camphor
- Phenolate sodium 0.5-1.5%
- Resorcinol 0.5-3%

Skin Protectants
- Allantoin
- Cocoa Butter
- Dimethicone
- Glycerin
- Petrolatum
- Shark liver oil
- White petrolatum

Often an affected individual cannot recall when he experienced his first fever blister. When an infection occurs on tissue adjacent to the lips or nose or another area of the body, it is referred to as a secondary infection.

Once infection has occurred, the virus may remain dormant in the body for the remainder of the individual's life, often resulting in subsequent herpetic lesions. It is thought that, between bouts of fever blister flare-ups, the virus harbors within the sensory ganglia neurons of the trigeminal nerve that innervates the site of the primary infection. The body's defense mechanism normally keeps the infection dormant. But under certain stressful conditions, the immune response will be lowered or distracted, and recurrent lesions can occur. Table 2 lists factors known to activate recurrent herpes infection.

Humans can develop partial immunity to the herpes virus, type 1. Most children are born with the same level of passive immunity as that of their mother. By the end of the first few months of life, this immunity disappears. At that point, children are especially prone to development of fever blisters. Around age five active immunity begins to develop due to continued exposure to the virus. If the body's immune system is fully operational and responsive, it will provide the individual with immunity by adulthood. Persons experiencing a primary herpetic infection generally will suffer recurrences throughout life.

The localized area feels firm due to local edema. Shortly, solid elevations of the skin appear, then blisters form. The area may appear reddened, because of capillary dilation. Lesions may persist for several hours before the blisters break. At that time, they take on the characteristic yellowish crusted appearance. Recurring episodes are usually less irritating that the primary blister. For the most part, they are mild and little more than annoying.

Blisters should not be arbitrarily broken. The fluid contains the infective virus and can transmit infection to other areas or persons. When blisters rupture, the victim should take special care to minimize contamination of other parts of the body or other persons.

Lesions normally heal in 7 to 10 days without scarring or further problems. On occasion, secondary bacterial infection appears, especially if lesions are large. The presence of pus under the crust of a fever blister indicates possible bacterial involvement. Whenever healing doesn't occur within two weeks, the individual should seek medical care. Persistent lesions may indicate the presence of more serious pathology.

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Self-Treatment of Fever Blisters with Nonprescription Remedies

Although it has been vogue over the years to treat fever blisters with astringents and other agents that deprive the virus of moisture, evidence of effectiveness for this form of therapy has not been substantiated as of the publication of FDA's TFM. Currently, safe and effective therapy (i.e., Category 1 drug product ingredients) is limited to protectants and external analgesics (Table 3).

There are no specific remedies for curing or preventing fever blisters, so primary treatment is directed at relieving symptoms. This includes lessening pain and decreasing the duration of lesions, and providing a protective effect. FDA's conclusions follow.

Safe and Effective Skin Protectants

Skin protectants that are safe and effective for self-treatment of fever blisters include: allantoin (absorbent); dimethicone (demulcent); cocoa butter, petrolatum, white petrolatum, and shark liver oil (emollients); and glycerin (absorbent, demulcent and emollient). These agents soften the crust on fever blisters and, therefore, relieve dryness. Their softening and moisturizing action keep fever blisters moist to prevent drying or fissuring. This, in turn, reduces the occurrence of secondary infections and offsets the delayed healing and discomfort caused by dry and cracked tissue in and around the fever blister. Manufacturers of OTC products will be permitted to claim that their products "soften crusts (scabs) associated with cold sores and fever blisters," and "relieve dryness and softens cold sores and fever blisters."

Safe and Effective External Analgesic Ingredients

Local anesthetics, and the alcohol/ketones listed in Table 3 are safe and effective for the temporary relief of pain and itching associated with fever blisters. The external analgesics cited in Table 3 can be combined with the skin protectants listed there also.

Other Ingredients

Drug ingredients that did not receive the safe and effective designation and cannot be labeled for treating fever blisters are antihistamines, hydrocortisone, and counterirritants. For antihistamines, the agency stated it had no basis to conclude that drug action on nullifying the effect of released histamine would relieve pain and itching of fever blister lesions. While antihistamines are claimed to be useful in alleviating some causes of itching and pain, there is no evidence of this specific use for fever blisters.

With respect to hydrocortisone, its current class labeling guidelines indicates that it is

Table 3

Representative OTC Products Containing FDA-Approved Ingredients for Fever Blister Symptoms

Product	Ingredient(s)
Benzodent	Benzocaine
Blistex	Allantoin, camphor, phenol
Campho-Phenique	Camphor, phenol
Herpecin-L	Allantoin
Lip Medex	Camphor, cocoa butter, petrolatum, phenol
MG Cold Sore	Lidocaine, menthol
Numzident	Benzocaine
Orabase/Benzocaine	Benzocaine
Orajel Mouth-Aid	Benzocaine
Pfeiffer's Cold Sore	Camphor, menthol
Tanac	Allantoin, benzocaine

effective in relieving inflammation and itching of responsive dermatoses. Fever blisters are not responsive to steroids. Counterirritants were also judged to be inappropriate for use in treating fever blisters.

Two astringents that were identified as safe, but at present still unproven, were tannic acid and zinc sulfate. Further studies are required to prove efficacy before either astringent can be added to the list of allowable OTC fever blister remedies.

Patient Advice

It is difficult to distinguish fever blisters from canker sores. Consumers nonetheless often ask pharmacists for advice. The goal of therapy is to alleviate pain and help the body heal itself as much as possible. There are no remedies to cure fever blisters. Generally, treatment differs for fever blisters and canker sores. Pharmacists can use the information in Table 1 to help differentiate between the two conditions in order to decide which OTC product is best. Table 3 lists OTC products for treating fever blisters.

Fever blister lesions should be kept moist to discourage cracking of the skin. Fissures increase discomfort, augment the chance for secondary infection, and prolong healing. Bland emollient creams serve this function. Products containing astringents should be avoided for treating fever blisters since they promote drying and cracking.

Fever blisters are self-limiting and usually clear within two weeks. Whenever they worsen with self-therapy, persist beyond two weeks, or continue to occur, medical advice should be obtained. Although they cannot be cured, fever blisters should not be ignored.

CORRESPONDENCE COURSE QUIZ

Fever Blisters

1. All of the following are classed as safe and effective OTC analgesics for use on fever blisters EXCEPT:

a. mepivacaine
b. lidocaine
c. benzocaine
d. juniper tar

2. Which of the following symptoms differentiates fever blisters from canker sores to the greatest extent?

a. Fever blisters cause swollen neck glands; canker sores do not.

b. Canker sores cause swollen neck glands; fever blisters do not.

c. Fever blisters cause intense pain; canker sores do not.

d. Canker sores cause intense pain; fever blisters do not.

3. All of the following terms refer to the herpes virus that causes fever blisters EXCEPT:

a. Hominis
b. Simplex
c. Labialis
d. Zoster

4. Of the following, which is classified as an absorbent, demulcent and emollient?

a. Allantoin
b. Dimethicone
c. Glycerin
d. Petrolatum

5. Patients suffering from fever blisters should be informed that fluid escaping from broken blisters:

a. is harmless and needs only be wiped off with a tissue.

b. contains the infecting virus and should not be allowed to touch any other skin surface.

6. The type of herpes virus that most often causes fever blisters is:

a. type 1
b. type 2

7. All of the following are classified as a safe and effective OTC skin protectant EXCEPT:
   - a. white petrolatum
   - b. camphor spirits
   - c. shark liver oil
   - d. cocoa butter

8. After a primary fever blister infection, the affected person will:
   - a. generally have recurrent fever blisters
   - b. rarely have recurrent fever blisters

9. Safe and effective OTC skin protectants reportedly accomplish all of the following EXCEPT:
   - a. soften fever blister crusts
   - b. keep fever blisters moist
   - c. prevent secondary infections
   - d. prevent fever blister recurrences

10. Keratoconjunctivitis refers to herpes virus infections that spread to the:
   - a. brain
   - b. eye
   - c. liver
   - d. skin

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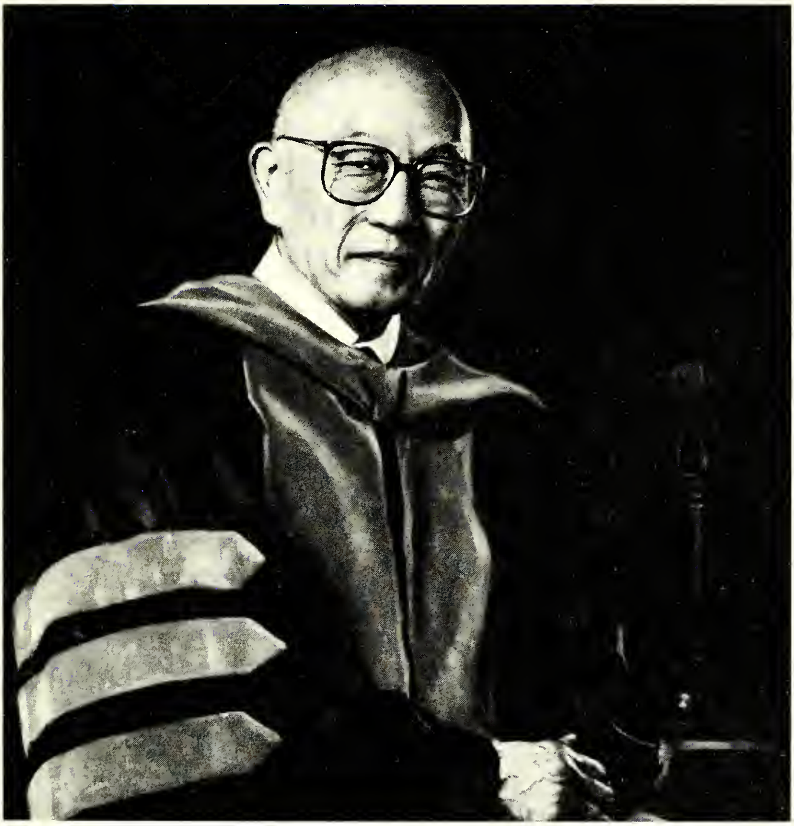

Oil Portrait of UNC Dean Tom S. Miya to be hung in Beard Hall. *Story on Page 5*

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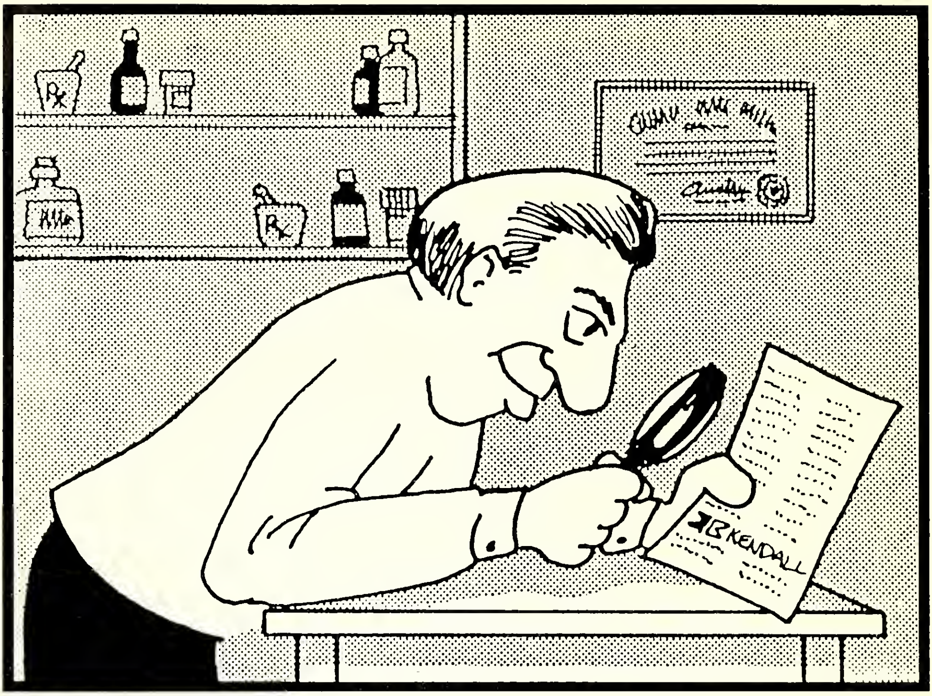

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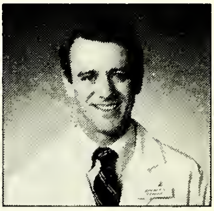
Important figures in diabetes care

7

Diabetes is the **No. 7** cause of death in the US[1]

1

Diabetes is the **No. 1** cause of new blindness in persons aged 20-74[1]



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1. *Diabetes Surveillance, 1980-1987.* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

TOM MIYA RETIRES AS UNC DEAN

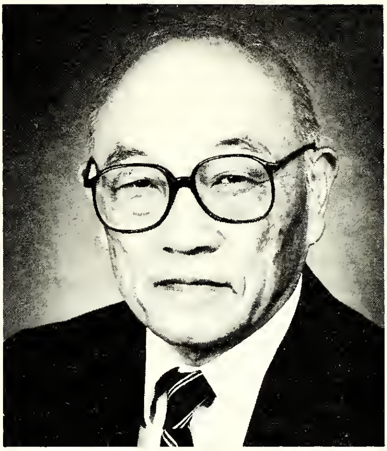
In January of 1977, a 53-year-old professor from Purdue came to the UNC School of Pharmacy poised to steer the program towards excellence. His background included education at Nebraska and Purdue as well as a brief stint in military intelligence.

On June 30th of 1992, that same man, whose vision and work ethics are unmatched, will retire from the Dean's chair after fulfilling his goal. That goal was to make the UNC School of Pharmacy one of the best in education, research and reputation. That man is Tom Saburo Miya.

His accomplishments were cited at a retirement dinner held in his honor on May 16, 1992. The celebratory event was held at the Morehead Planetarium Banquet Hall on the campus of UNC. It was an opportunity to share with Dean Miya and his friends the memories of his influence on pharmacy.

With Ralph P. Rogers Jr., former long-time president of the Pharmacy Foundation of North Carolina, as Master of Ceremonies and opening remarks by UNC Chapel Hill Chancellor Paul Hardin, the program was off to a fast start. Betty H. Dennis, president of the North Carolina Pharmaceutical Association, gave the invocation. 1991 graduate Scott Ballenger quoted former students whose dreams were reached with the help of Dean Miya. He was there to encourage and to challenge them to reach their best for pharmacy, said Ballenger

Gary Yingling, president of the UNC School of Pharmacy Alumni Association, continued, remembering his days as a Masters candidate in pharmacology under Dr. Miya, and how much he cared for all of his students. "They were all treated special." Fred Eckel, a professor at the school since 1966, emphasized that the Dean's job was not easy but that Dr. Miya had survived and "engraved himself on many hearts along the way."



Garland Hershey, Vice Chancellor for Health Affairs, spoke highly of Dean Miya's accomplishments as an administrator and the meteoric increase in extramural funding during his tenure. Finally, Dean Miya's daughter, Pamela, offered her insight on Miya as a family man. She noted his love, his caring, and his willingness to always take a moment to listen to her needs and offer appropriate advice.

These five speakers painted a beautiful image of Tom Miya, drawing from all facets of his life to give those in attendance a better understanding of the man who manned the controls of the UNC Pharmacy School for the past fifteen years.

While he will be gone, he will not be forgotten. The dinner raised over $75,000 which will endow a fund in his name, supplying resources to the School of Pharmacy for years to come. In addition, there are also funds in the Miya name for an undergraduate scholarship and a toxicology fund.

A portrait of Dean Miya in his academic regalia, painted by Dean Paules, was unveiled by Pamela U. Joyner, president of the Pharmacy Foundation of North Carolina, Inc., and accepted by Associate Dean George Cocolas, on behalf of the School. It will hang in the School to remind others of the rich past of pharmacy education in North Carolina.

While there are many physical things to remind us of Dean Miya, history will show how a man with foresight guided a pharmacy education program through hard economic times and through difficult professional issues. His hand held steady throughout. Thank you, Dean Miya.

A CONVERSATION WITH THE DEAN

by Keith Chisolm, UNC School of Pharmacy, as part of his internship rotation through the NCPhA office

For nearly an hour and a half, Dean Miya and I discussed issues concerning his tenure as dean, and the future of the UNC School of Pharmacy. The facial expressions alone would have been sufficient to answer the list of questions I posed to the Dean. His face gave responses of concern, hope, pensiveness, joy, excitement, and pride. Nearly all of his answers were in the collective "we," giving testimony to his strong sense of patriarch-ship within the school. Even after the formal part of the interview ended, we continued to talk a bit about pharmacy education and ethics issues, subjects that I discovered he is very adamant about.

Journal: *What do you plan to do during your retirement?*

Dean Miya: "I really have not decided yet; there are some personal things that I finally want to take care of. I want to do some writing in the area of pharmacy education, particularly with an emphasis on ethics." Ethics, and particularly ethics in pharmacy practice, is a subject that Dean Miya has an affinity for.

What were your goals? To make this school first-class in teaching and research. I am not entirely satisfied with the current status, but we have come a long way.

Biggest accomplishment? [he had to think for a minute] {he spoke not of personal success, but of the accomplishments for the school} "That we have moved on all fronts, and not focused the school on one point or area—a balanced approach. There are not many excellent, balanced programs in the country like UNC. All departments within the pharmacy school are good. There is a good graduate program, good student body. The Pharmacy Foundation has increased ten times, and the extramural funds of the pharmacy school have increased in order of magnitude. All things are in place." Dean Miya has seen the start of the Pharmacy Alumni Association, and helped start it himself. Membership has grown to a little less than 5,000 members. (I was surprised to find out that there was no Alumni Association before he came to UNC!) The Pharmacy Alumni Association will come under the Pharmacy Foundation, to produce more of a synergy. Hopefully as a result, they will take more of a role and interest in the Pharmacy School and its students. The maturing of this union will be and should be an important component of the future of the school.

Biggest disappointment? Frustration rather than disappointment; one common to all deans, is the continuing struggle for state funds and support. One disappointment that he took to heart was the/his inability to transmit to faculty across the board what we are about, that our goal is to put out a good product (student), and the lack of communication, similar to the problem the school has.

If you had more time? "I would change the school to all Pharm.D. tomorrow. But with that comes other concerns and extramural degrees, additional clerkships development, and this takes time. More research potential within the school. Also one task would be to promote the school more within the state. I believe the pharmacy school is more respected and well-known outside the state than within. It's time to do a better job of tooting our own horn (not bragging) and tell people what we're doing and what we're doing for them."

Times you wished you weren't dean? {jokingly} "Yeah, but only lately. No, not a day that I have come into school reluctantly. I've had a great time, great support. I'm usually one of the first to arrive every morning."

Miss the most? The contacts with the students, undergrad and grad. He "mentored" over 100 graduates while at Purdue; they still call and write often just to keep in touch. {laughingly} "I get a kick out of students that I taught 25-30 years ago and who still write to request letters of recommendation."

Funny stories? There's probably no one else in the country, as far as pharmacy school administrators, who know how to milk (by hand) a tom turkey to get semen for artificial insemination to fertilize the hen turkeys. {he goes on to explain} They have a problem, from so much inbreeding, it's difficult for them to reproduce...Do you know how thick their semen is? About as thick as honey on a cold day.

What he's learned. "You can't change things overnight" and "you can't be a ship without a rudder," "a lot of small decisions must take place in order to affect change. People have a great influence on your outcome. I have been lucky to have had good mentors, share of personal glory."

Minority faculty —"Within the context of diversity, you must have excellence, must be competitive globally. We have an agreement with Xavier to fund a student to come in the summer and work with faculty here. Hopefully that student goes back and spreads the good news about UNC. It's a way to let others know what we are doing and to find out what others are doing. But there is a need to do more."

Future changes —"The profession of pharmacy has been our own worst enemies. Changes are taking place with the discerning of distributive vs. cognitive services and how those differences need to be addressed. Reimbursement issues. But this school will be adequately equipped to face them."

Future challenges—"The school will need more corporate support with the mandatory change to all Pharm.D., we're changing our *modus operandus.* There will be a need for the school to become more efficient, we are already having faculty members do many things. In concentrating on the quality of education, here, close attention is paid to undergraduates. Newly mentioned additions are the microcomputer room, satellite classrooms in which teleconferences can be held, and smaller, more interactive contact classes. The future will see computer-assisted teaching, in addition. The pharmacy school must strive to maintain exceptional standards. The success of the school and the success of the practitioner are linked. A strong school will produce strong practitioners. It's {all} linked. As soon as the profession realizes this, the better. When I went to Nebraska, it was four years of pharmacy school, from freshman year to senior year straight through. Only later did they go to having students go through general college. Though it's a 5 year total process, now we only have three years (2 1/2, as each student goes on rotations for a semester) to "brainwash" students. It's less than I had; I don't think its enough. There needs to be a vision of the future, with the doubling of scientific knowledge every four years or so. To put it into perspective, I say the introduction of penicillin (during WWII when it was being recovered from urine for reconstitution), now look at all the antibiotics. You're really going to see a lot in your practicing lifetime. There is going to be a lot in the way of bioethics in these bioengineered products, i.e., with England not giving transplants to anyone over 50 based on life expectancy and productiveness, for example, the issue of fetal transferred tissue."

Advice—"never smooth out corners too much," meaning play by the book, the rules. Sometimes it takes more effort to be dishonest than to be honest. Always be ethical in what you do. I've seen many cases in which dishonesty catches up with people. "Work hard, put your time in, quality time" whatever the word work actually means.

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Clinton Rogers, *right*, presents Frances Sinnett with the Ralph Peele Rogers Award for excellence in Pharmacy Administration. Assisting are Ralph P. Rogers Jr. and Betsy Rogers Millar. *Photo by Qualex*

Program participants in the Ralph Peele Rogers Award Dinner held at the Carolina Inn were, *left to right,* UNC School of Pharmacy Associate Dean George H. Cocolas; Frances Sinnett, the award recipient; Division of Pharmacy Administration Chairman Joe Norwood, and NCPhA Executive Director Al Mebane. *Photo by Qualex*

EDUCATION OF THE PHARMACY TECHNICIAN

(As A Result Of The 1990 Omnibus Budget Reconciliation Act)

by Frances Sinnett, 1992 Ralph Rogers Award Recipient

Certification of pharmacy technicians by each State Board of Pharmacy following completion of training programs provided under the direction of registered pharmacists should be implemented to properly accommodate the changes in community pharmacy. The pharmacist will now face mandatory counseling. This responsibility will be added to the many challenges a pharmacist must face. Daily, the pharmacist is confronted with pressures of today's fast paced world; difficulties with unhappy customers, disagreements with other health professionals, the struggle to balance professional responsibilities with those of retail, promotion of workable relationships with employees, and the maintenance of a clean, well-stocked pharmacy that turns out the volume demanded of it with quality. How can the pharmacist perform the task of mandatory counseling along with all else that is asked of him? The pharmacist must have the time to direct attention toward counseling patients, and therefore, some responsibilities should be shifted to the pharmacy technicians. To insure the quality of the technician's work, and thus the pharmacist's confidence in the technician, some type of guided training and skills assessment is necessary.

Increased patient counseling in community pharmacies came about in 1988-89, when the National Association of Boards of Pharmacy (NABP) developed a model regulation which included counseling. Arkansas' Democratic senator, David Pryor, went beyond the NABP's move and incorporated mandatory Medicaid patient counseling as a part of the Medicaid Pharmaceutical Prudent Purchasing Provisions legislation, which was passed as part of the 1990 Omnibus Budget Reconciliation Act (also referred to as the Medicaid Drug Rebate Law). As a result of this legislation, effective in 1993, pharmacists will be federally required to counsel all Medicaid patients.

The benefits of mandatory counseling are numerous, and some of them are as follows: the quality of patient care, the patient's quality of life, and patient compliance may be increased, whereas, the number of hospital stays and admissions, the cost of health care and the number of treatment failures may be decreased. There are benefits for the pharmacist as well. Counseling will allow pharmacists to reach their professional objectives of maintaining the patients' good health through prescribing preventive measures on how to decrease the risks associated with diseases, and providing education on medications which may increase the patients' compliance and awareness of their conditions. However, counseling requires time and attention to allow for more lengthy, open communication with patients.

A situation that must be dealt with concerning patient counseling is the deletion of some of the pharmacist's tasks to make him available to counsel patients, and assigning someone the responsibility of that workload. One solution is to pass some of the responsibility to the pharmacy technician. Employing pharmacy technicians saves the pharmacy money from hiring another registered pharmacist to take part in the added responsibility. Richard P. Kusserow, inspector general of Health and Human Services, encourages greater use of technicians in community pharmacies, believing that technicians "...performing routine duties, such as filing stock orders and maintaining patient profiles cut pharmacy costs, and free pharmacists for more critical tasks such as counseling." (1) Relying on pharmacy technicians to perform tasks, such as order entry, compounding, stocking, packaging, labelling and billing, is feasible and has been done for many years in hospitals. One argument against increasing the responsibilities of the technicians is that the technicians are not trained well enough to be depended upon to carry out acceptable work. Thus pharmacy technician training programs should be provided.

The American Society of Hospital Pharmacists (ASHP) has accredited thirty technician training programs in the United States.(1) One program instituted at the Academy of Health Careers, Inc., in Oak Park, Michigan, staffs eight pharmacists and one pharmacy certified technician (PCT). The program accepts high school graduates and exposes them to sixteen weeks of didactic training followed by four weeks of supervised clinical work at surrounding hospitals.(3) An example of the subjects included in their curriculum include: "terminology, pharmacology, the practice of pharmacy, [and] dosage calculations."(3)

Durham Tech Community College also offers a pharmacy technician training program. Approximately twenty-two students enroll in the program which spans three quarters. They, too, accept only high school graduates, yet find that many of their students have additional education.(4) According to Don Kritsch, the technician specialty program director at Durham Tech Community College, registered pharmacists teach all pharmacy-related courses. Other courses in the program are taught by the school's general faculty. The curriculum includes subjects such as pathophysiology, microcomputers, mathematics, typing, pharmacology, community pharmacy and hospital pharmacy. The community pharmacy class incorporates a four-hour rotation each Friday for one quarter at local chain community pharmacies. The registered pharmacists at these community pharmacies have been very receptive to and grateful for the students' assistance. Students must also perform a hospital rotation for eight hours a day, three days a week during their final quarter. Students are awarded a certificate of completion at the end of the three quarter program.(4)

Education of pharmacy technicians should be of importance to the general public, pharmacists, and technicians themselves. Frances Parker, a school teacher in Newton, North Carolina, is a mother of seven and a grandmother of ten. When asked about technicians and education, she answered, "As a member of the community, I would like to have educated people behind the filling of my prescription—pharmacist and technician."(5)

Two local chain store pharmacists shared similar views on the education of technicians. Chuck Hamrick, a pharmacist at Eckerd Drug, said that although they use pharmacy students as their technicians, he does support the education of technicians. He said that it was evident that their store does too, because they act as a back-up rotation site for Durham Tech Community College's community pharmacy class.(6)

A pharmacist from Revco Drug Stores admitted to feeling spoiled by having pharmacy students as technicians. She said that hiring untrained technicians was more difficult because of the extra time, training and energy involved before being able to feel comfortable and secure with the work of the technician who lacks formal education.(7) Bill Mixon, a hospital pharmacist in Hickory, North Carolina, believes that a technician needs to "develop a body of knowledge, a sense of profession, before he/she can go forward."(8) Technicians should support education for themselves because it would allow them to be recognized as more of a professional.(8) Duane Barron is a hospital pharmacy technician who is the co-founder and president of the Unifour Chapter of the American Association of Pharmacy Technicians (AAPT). Baron believes that the job of the technician must change to accommodate and complement changes in the role of the registered pharmacist.(9) He added that, "Technicians feel the need to be educated so that they may view their job as more of a career, and so that they feel confident and competent enough to aid the pharmacist in whatever way needed."(9)

Education and training programs need a direction and a purpose in order to be used effectively. The purpose (to better aid the pharmacist with his responsibilities) has already been discussed. The direction, however, appears to be unclear. If a person completes an accredited pharmacy technician training program, what is the product? One pharmacist believes that "Education is a good idea, and that [technicians] should be certified so that their education has meaning."(7) Bill Mixon asked, "What is certification? It doesn't mean that technicians all know the same thing.

Perhaps a national minimal standard is needed to define certification".⁽⁸⁾ Duane Barron said that people in his organization agree with Mixon and that the goals of AAPT include setting a standard, practicing that standard and getting recognition for performing a better job.⁽⁹⁾ Barron stated that "Pharmacy technicians are one of the few, if not the last, members of the allied health field to gain certification, and that we should be [certified] in order to become a more integral part of the team of health care practitioners."⁽⁹⁾

The 1991 American Pharmaceutical Association (APhA) House of Delegates discussed the need for and future of technicians at their Annual Meeting. They reaffirmed their 1988 statement of opposition of the "licensure, registration, or certification of pharmacy technicians by state of regulation…," believing the "…pharmacists—not state or federal authorities—should have control over the guidelines and standards for pharmacy technicians…"⁽¹⁰⁾ The APhA did adopt policies which support "…the voluntary certification of pharmacy technicians by the pharmacy profession…," and also "…the voluntary accreditation of pharmacy technician training programs by the pharmacy profession…"⁽¹⁰⁾ Accredited pharmacy technician programs employ registered pharmacists to teach all pharmacy-related courses and were accredited by representatives of the pharmacy profession (ASHP). As the counseling role of pharmacists increases, APhA may be forced to further define the guidelines and standards for pharmacy technicians by implementing a certification of pharmacy technicians. They have agreed to voluntary certification "by the pharmacy profession," yet have not specifically defined anyone to head the certification process. Many believe that this task would be most appropriately handled by each State Board of Pharmacy. This possible solution must be investigated so that the progression of health care services may continue.

It is evident that the pharmacist faces demanding tasks on a daily basis. As of 1993, mandatory counseling will be added to this list of obligations. In order to perform his profession with quality, the pharmacist must shift some of his duties to the pharmacy technician. The technician must be trained and certified to adequately carry out a defined role in community pharmacy. Certification and training guidelines for pharmacy technicians should be employed in response to mandatory pharmacy counseling. These guidelines might best fall under each State Board of Pharmacy jurisdiction.

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LETTERS OF INTEREST

United States Senate
Washington, DC 20510-3304

Mr. Sam Burrus
24 Park Street
Canton, North Carolina

Dear Sam,

Thank you for your letter regarding the McCarren–Ferguson Act. I appreciate hearing your thoughts on this issue.

As you know in the 102nd Congress, both the House and the Senate have pending legislation that would repeal or amend significantly the McCarren–Ferguson Act. All these bills address the exemption from antitrust laws the Act affords the insurance industry since its passage in 1945. Opponents of McCarren–Ferguson claim that such an exemption from antitrust laws have adversely affected the insurance industry's competition and its consumers.

I share your concern and desire for greater competition in and more consumer choice for insurance products. However, it is not yet clear to me that a simple repeal of the McCarren–Ferguson Act is the best way to accomplish these goals.

Currently, S. 430, the Insurance Competitive Pricing Act, is in the Senate Judiciary Committee. I will watch very carefully any hearings on this bill to determine the most appropriate way to achieve greater competition in the insurance industry.

With best wishes always,

Sincerely,
Terry Sanford

Those interested in convincing Senator Sanford and others of the urgency of HR. 9 and S. 430 should take time now to write and express their views.

NARD SEEKS STUDENT AFFAIRS DIRECTOR

NARD is seeking a recent pharmacy school graduate to manage student affairs within the Department of Professional Affairs. Responsibilities include convention planning, coordinating student chapters, serving as a liaison to pharmacy schools, and assisting with student activities of the NARD Foundation.

Candidates must have excellent oral and written communication skills and past leadership in pharmacy organizations.

Please send resume by September 15, 1992 to: Personnel Department, NARD, 205 Daingerfield Road, Alexandria, VA 22314

APPLICANTS SOUGHT FOR APHA/NCSPAE EXECUTIVE RESIDENCY PROGRAM

The American Pharmaceutical Association is seeking applicants for the 1993–1994 Executive Residency in Association Management The residency begins in July 1993 and is a post graduate training program conducted at the ASPhA office in Washington, D.C., and a selected state association office.

The resident will spend nine months at APhA headquarters and three months at the state association office, learning management functions of a national and state organization.

Applicants must be graduates of an accredited school of pharmacy and be licensed or immediately eligible for licensure following graduation. They must submit a letter of application stating why they are interested in pursuing the residency, a resume, and two letters of recommendation. At least one letter must be professional and one may be academic. The application must be postmarked prior to December 1, 1992. For more information, contact Jan Hinkle, APhA/NCSPAE Executive Resident, APhA, 2215 Constitution Avenue NW, Washington, DC 20037.

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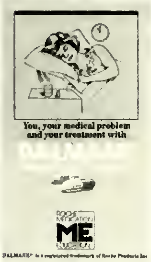
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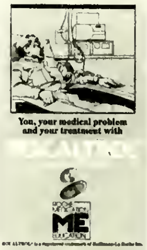
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PHARMACY LAW CAPSULE

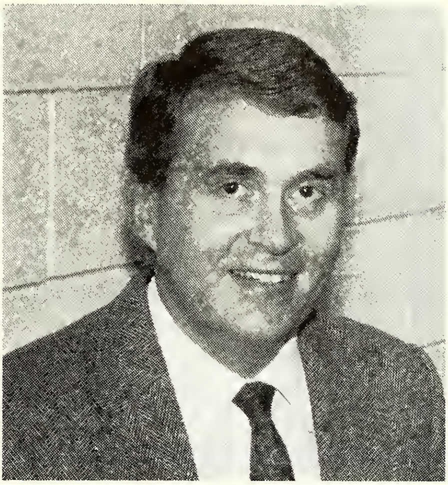
by James A. Boyd, Pharm. D., M.B.A.
Assistant Professor
Department of Pharmacy Practice
Campbell University School of Pharmacy

FDA DEFINES COMPOUNDING AND MANUFACTURING

The Food and Drug Administration (FDA) recently released guidelines on compounding and manufacturing. In the pervious column of Pharmacy Law Capsule the proposed draft definitions provided by the National Boards of Pharmacy (NABP) were discussed. The draft "model state pharmacy act" defining pharmacy compounding and manufacturing was endorsed by many pharmacy organizations.

In NABP's draft definition it appeared that the key issue was promotion and marketing of drugs or devices. When a company actively promotes a product it gravitates into the category of manufacturing. Also, important to note; pharmacists may inform practitioners and patients of compounding services without crossing into manufacturing. After the NABP's draft was presented to the FDA, the FDA released guidelines and policy statements regarding compounding and manufacturing. (March 16, 1992, FDA Compliance Policy Guides 7132-16)

As reported in the release, the FDA believes that an increasing number of establishments with retail pharmacy licenses are engaging in manufacturing, distributing, and promoting unapproved new drugs for human use. The FDA believes that the manner in which this activity is occurring is clearly outside the bounds of traditional pharmacy practice and that this practice constitutes violations of the Food Drug and Cosmetic Act. The promotional activities include employing detail persons and hiring marketing consultants to promote the company's specialization of compounding specific products or therapeutic classes of drugs. The firms also receive and use large quantity bulk drug substances in order to manufacture unapproved drug products, and to manufacture drug products in large quantity. This is done in advance of receiving a valid prescription for the products. Also, the firms serve physicians and patients with whom they had no established individual or professional relationship.


James A. Boyd

There is potential for causing harm to the public health when products are manufactured and distributed without FDA approval, adequate record keeping, and adequate controls for safety, and the purity, potency, quality, and identity of the drug product are a matter of concern. The FDA released policy statements which describe activities which are considered to be manufacturing. The following is a list of the activities:

1. Soliciting business (e.g., promoting, advertising, or using salespersons) to compound specific drug products, product classes, or therapeutic classes of drug products.

2. Compounding, regularly, or in inordinate amounts, drug products that are commercially available in the marketplace and that are essentially generic copies of commercially available, FDA-approved drug products.

3. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the

substance has been made in an FDA approved facility.

4. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

5. Using commercial scale manufacturing or testing equipment for compounding drug products.

6. Compounding inordinate amounts of drugs in anticipation of receiving prescriptions in relation to the amounts of drugs compounded after receiving valid prescriptions.

7. Offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

8. Distributing inordinate amounts of compounded products out of state.

9. Failing to operate in conformity with applicable state law regulating the practice of pharmacy.

Also included in the release was the recognition that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of drugs upon receipt of a valid prescription for an individual patient from a licensed practitioner. This traditional activity is not subject to the new policy.

In conclusion, the FDA release deviated from the draft NABP statements which has raised some concerns. The Washington Legal Foundation, a foundation dedicated to fighting government excesses, has petitioned the FDA to seek public comment before it adopts rules distinguishing drug compounding from manufacturing.

(Rx Ipsa Loquitur, May 1992).

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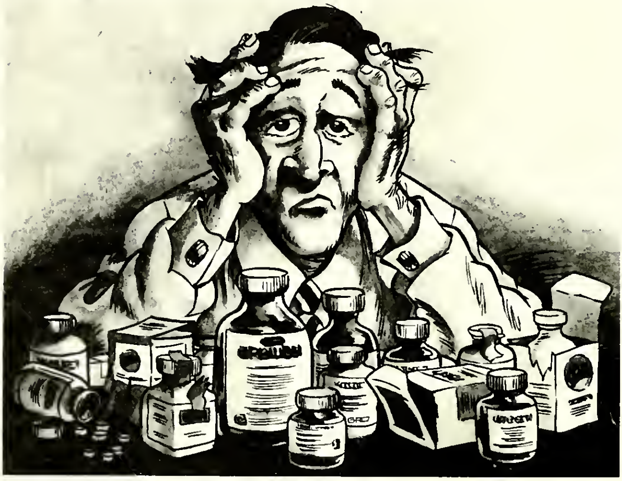

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AN INTERNATIONAL PHARMACY STUDENT EXCHANGE PROGRAM

by Eric Wolford

The basic goal of health care, and in particular, of pharmacy in the United Kingdom is much the same as it is in the United States: provide the best possible care at the lowest possible cost. The manner in which that goal is approached, however, differs in many ways between the countries. Recently, myself and fellow classmates Beth Steinbeck, Kelly Sevier, Lisa Chang, and Donna Cook, experienced those differences first-hand while participating in the UNC–Welsh School of Pharmacy Internship Exchange Program in Cardiff, Wales.

Cardiff sits on the Bristol Channel and occupies the southern-most point in Wales. The city's turn-of-the-century reputation as the largest coal exporter in the world produced one of the most significant metropolitan areas in Great Britain.

Today, the mining industry in Wales is virtually nonexistent, and Cardiff's economy now relies heavily on its rich tourist trade. With its historic city buildings and parks, an 11th century Norman castle, and one of the finest centers of arts, education, and commerce in the country, Cardiff provided an excellent backdrop for our experience.

The exchange program between UNC and the Welsh School of Pharmacy at Cardiff College began in 1988, allowing students from each university to study health care abroad. Our program began on May 19, and consisted of four weeks of lectures and rotations designed to familiarize participants with aspects of pharmacy in the U.K. Included were visits to several health care facilities throughout southern Wales, such as St. Lawrence Hospital in Chepstow.

A former Italian and German prisoner-of-war hospital, St. Lawrence is now a burns and cosmetic surgery unit, serving residents throughout the Wye Valley, and managing everything from hot tea burns to complete reconstructive cosmetic surgery. Although the hospital appears as it probably did during World War II (barrack-like buildings with cement floors), patients spoke highly of the care they received. Other hospitals (Cardiff Royal Infirmary, Llandough Hospital, Heath Hospital) presented similar scenarios: drab, antiquated surroundings, but highly regarded patient care.

It seemed clear, then, that the general lack of flash and glimmer at facilities in the U.K. was not indicative of inadequate provision of care, but instead only reflective of the tight purse strings of the National Health Service.

It is interesting to note, however, that the National Health Service pays for breast reductions, tattoo removals, breast implants, and even liposuction at hospitals like St. Lawrence.

Community pharmacy is very similar between the two countries. Most stores in the U.K. are computerized, and patient counseling occupies a considerable portion of the pharmacist's time. The major difference is that pharmacists are essentially paid by the National Health Service.

Prescriptions filled under the National Health Service (at least 80% of all prescriptions in the U.K.) are bundled and sent to a government facility at regular intervals. Here the prescriptions are sorted and evaluated, and payment to the pharmacy is made based on government contracted prices for each particular medication. Under this system, reimbursement takes two to three months, and original prescriptions cannot be kept on file in the individual stores.

For me, the most striking difference in pharmacy between the U.S. and the U.K. existed in the education of pharmacists. College programs consist of three class years, each broken into three ten week terms. Examinations are given only at the end of each school year, and are entirely essay in nature. Students who score below passing in a particular area are subject to *oral* make-up examinations. Since grading is essentially pass/fail, students are not preoccupied with grade point averages and class rankings, as they are in the U.S.

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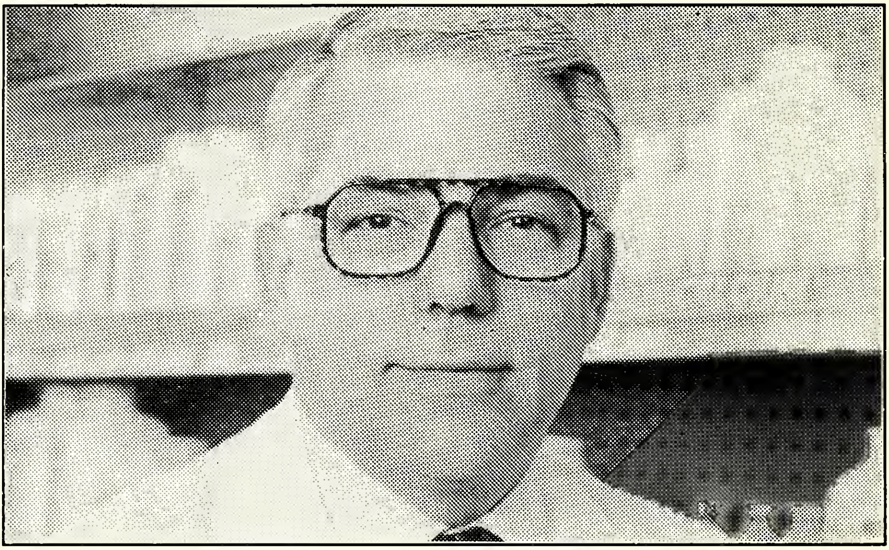

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The college program is followed by a one year internship in hospital or community pharmacy and, upon successful completion, the student registers with the Royal Pharmaceutical Society as a practicing pharmacist. Currently, there is no mandatory competency exam for prospective pharmacists, although classes graduating after 1992 will be required to pass a standardized exam before they can register to practice.

Continuing education, however, is still voluntary in the U.K., and according to polls conducted by the Welsh Center for Post-Graduate Education, only 60% of hospital pharmacists and 28% of community pharmacists in Wales participate.

All in all, the UNC–Welsh exchange program offered us an opportunity not obtainable from any lecture hall or textbook. We lived, worked, learned, and became part of the Welsh culture. In the end, we gained a better understanding and appreciation for our own health care system, and a lifetime of memories we will never forget.

FACTS AND COMPARISONS ANNOUNCES INFOBASE

Facts and Comparisons announces the release of its new **InfoBase** modules, a family of computer-based drug information resources. The series of modules allows rapid access to extensive data on a broad range of drug-related topics and can be integrated into existing computer systems by software vendors.

Patient Drug Facts InfoBase is the patient counseling module and will be released in September 1992. It will produce single-page, personalized monographs in patient-friendly language. This module checks multiple drug-drug and drug-food interactions. For more information, contact Facts and Comparisons at 800-223-0554 or your software vendor.

Participating in the Exchange Program and seen on the floor at Heath Hospital in Cardiff, Wales, are Eric Wolford, Lisa Chang, Donna Cook, Beth Steinbeck and Kelly Sevier. Not pictured are Bob Schollard from the UNC PI Development Program and Don Marsh, Director of Pharmacy Education, Mountain AHEC.

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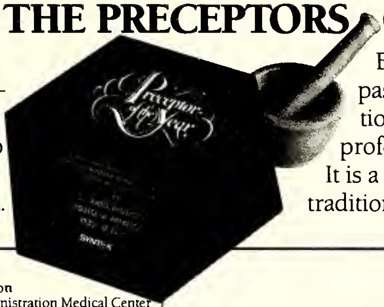

By example, these preceptors pass along to the next generation of pharmacists the highest professional ideals and standards. It is a service worthy of the finest traditions of pharmacy.

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N.C. MUTUAL WHOLESALE DRUG COMPANY HOLDS ANNUAL STOCKHOLDERS MEETING

N.C. Mutual Wholesale Drug Company held its 39th Annual Stockholders Meeting on May 20, 1992. President Robert Bowers reported record sales of over $220,000,000 and record rebates paid to stockholders for the year. These records were achieved despite the current economic climate and the intense pressure on profits created by a decline in opportunities for investment buying and low interest rates.

The following people were elected to new 3-year terms on the Board of Directors: Robert Bowers, Ronny Buchanan, Tommy Davis, Bill Mast, and Larry Denning. John Kerr, Kerr Drug Stores, was elected to complete the remaining two years on the seat vacated by Mr. Marion Edmonds, who resigned from the Board last November. Mr. Edmonds, Edmonds Drug, Greensboro was honored with a plaque in appreciation for his many years of service on Mutual's Board of Directors.

Mutual Drug is presently expanding its warehouse by 46,000 square feet and simultaneously implementing a new data processing system. These projects should be completed in 1993. The end result will give Mutual's customers a more efficiently operated warehouse with state-of-the-art management programs.

RAY A. WOLF NAMED PHARMACY RELATIONS DIRECTOR OF BURROUGHS WELLCOME CO.

Burroughs Wellcome Co. announced the appointment of Ray A. Wolf, Pharm.D., to the new position of Director, Pharmacy Relations and Educational Services.

"The new position of pharmacy relations director underscores the strong commitment that Burroughs Wellcome Co. has always had to pharmacists and their profession," said Mark Perrin, vice president, marketing and sales.

Wolf received his bachelor of science in pharmacy degree from Ohio Northern University College of Pharmacy and his doctor of pharmacy degree from the University of Kentucky College of Pharmacy. Following a residency at the University of Kentucky, Wolf was appointed assistant professor of pharmacy at the University of Arizona. He also completed a post-doctoral research fellowship at the University of Alston in Birmingham, England

Ray A. Wolf

His industry experience includes Key Pharmaceuticals and ICI Pharmaceuticals Group where he was director of pharmacy affairs. Wolf is a member of the professional relations committee of the National Pharmaceutical Council and a member of the advisory board of the American Association of Colleges of Pharmacy. He was a member of the board of directors of the Delaware Pharmaceutical Society prior to joining Burroughs Wellcome Co.

A native of Ohio, Wolf is registered to practice pharmacy in Ohio, Arizona and Delaware. He and his family will live in Chapel Hill.

WARNING: HOT WEATHER A HAZARD FOR OLDER PEOPLE

National Institute on Aging

National Institutes of Health • U.S. Department of Health and Human Services

Summer is the time for trips to the beach, picnics, and recreation. But for older people, hot weather also poses a special problem.

With age, the body's natural cooling system loses its effectiveness. During hot weather or vigorous activity the body normally perspires and moisture evaporating from the skin cools the body down. In later years the sweat glands work less efficiently, producing less perspiration and less efficient cooling.

The most serious result can be heat stroke, one form of hyperthermia. Heat stroke is a medical emergency that requires immediate attention and treatment by a doctor. Symptoms include nausea, dizziness, confusion or slowed-thinking, and lethargy (inappropriate sleepiness); and may progress to a coma. A person with heat stroke is usually dry, without sweating, and has a temperature of over 104° F. Treatment includes drinking cold (not iced) water and applying ice packs or wet towels to the body, with careful monitoring by a physician.

People experience hyperthermia in different stages. An early, milder form is heat fatigue, which is a general feeling of weakness. Heat exhaustion, caused by the loss of body water and salt, may develop more slowly. Symptoms of heat exhaustion are weakness, heavy sweating, nausea, and giddiness. Treatment is bed rest in a cool location, preferably in air-conditioning, and cool liquids. Water and fruit juices are best.

Hyperthermia poses an even greater risk for older people with chronic conditions such as diabetes mellitus and heart, lung, and kidney disease. Short-term illnesses, causing weakness or fever, can also place a person at higher risk. Certain kinds of medications increase susceptibility, as well. Diuretics, sedatives, antidepressants and tranquilizers, anticholinergic drugs, antihistamines, drugs for Parkinson's disease, and heart and blood pressure medications may alter a person's ability to perspire. Obesity and alcoholism also increase the risk of a heat-related illness.

To reduce your chances of getting hyperthermia, the National Institute on Aging offers the following tips for staying cool:

- Drink plenty of water and juices, but avoid alcoholic beverages
- Cool off by taking frequent showers or splashing yourself with water
- Wear light-weight, light-colored, loose-fitting clothes
- Avoid vigorous activity during the hottest part of the day (noon to 4 pm), but keep up your exercise program; find a cool, practical way to continue working out
- Wear a hat or use an umbrella if you must be out in the sun
- Use fans and air conditioners liberally; if no air conditioner is available, keep shades down and curtains drawn during the day, and windows open at night
- Visit air-conditioned places such as shopping malls, libraries, and theaters; but try to avoid crowded areas
- Avoid eating heavy meals; and limit the use of your oven
- If you have a chronic disease or take prescription medicines, talk to your doctor about possible heat-related problems.

For more information about hyperthermia, call 1-800-222-2225 to ask for our free brochure; or write to the NIA Information Center at PO Box 8057, Gaithersburg, MD, 20898-8058.

PHARMACY COALITION CLARIFIES CLIA REQUIREMENTS

Reprinted with permission from HHC (Home Health Care) Pharmacist Vol. 1, No. 7

At first glance, regulations released in recent months by the Health Care Financing Administration implementing the Clinical Laboratory Amendments of 1988 (CLIA) appear to create major barriers to the future of pharmacy health screening programs.

NARD, in coalition with the American Pharmaceutical Association, the American Society of Consultant Pharmacists, and the National Association of Chain Drug Stores, decided to take another look. The group submitted joint comments to HCFA to resolve some fundamental questions about CLIA, and participated in a recent meeting with HCFA Laboratory Branch Chief, Judy Yost, who is overseeing the implementation of these sweeping new regulations.

The groups asked for clarification on whether pharmacists could comply with the personnel requirements under CLIA to conduct moderately complex tests, such as blood cholesterol screening.

According to Yost, a pharmacist can qualify as a lab director under CLIA if he or she has earned a bachelor's degree and has at least two years of supervisory experience and two years of previous screening experience.

Yost also told the coalition that a pharmacy can continue to provide health screening programs or other lab testing on-site if the screening staff, testing procedures, liability, responsibility, and follow-up are provided by a contracting lab services company. In this scenario, the pharmacy itself would not have to qualify as a clinical laboratory because the contracting lab services company would itself qualify.

The coalition also asked for HCFA to reconsider its decision to include blood cholesterol screening among the list of "moderate complexity" tests. Pharmacists would need to come into full compliance with CLIA regulations (or subcontract with a certified lab) to perform any moderately complex test.

HCFA should consider re-categorizing cholesterol tests as one of a short list of "waived" tests, the pharmacy groups urge. "Pharmacists, who often provide cholesterol screening in their stores, are in a unique role to aid in the early detection of diabetes, hypertension, and hyperlipidemia," the groups told HCFA, adding that patients are likely to seek out more costly testing alternatives, such as clinics, physician's offices, or laboratories if their pharmacist is no longer able to conduct cholesterol screening.

According to Yost, reclassification of cholesterol testing may be possible at a later date because the list of tests performed and the various categories of the individual tests will be subject to periodic reviews.

Currently, only eight tests are eligible for a certificate of waiver: blood glucose testing, non-automated dipstick or tablet urinalysis, fecal occult blood screening, ovulation tests using visual color comparisons, urine pregnancy tests using visual color comparisons, erythrocyte sedimentation rate, hemoglobin by copper sulfate method, and spun microhematocrit. Without a waiver, facilities conducting these tests will need to comply with extensive quality control, quality assurance, patient test management, personnel, and proficiency testing requirements. The certificate of waiver costs $100 a year.

The CLIA regulations, designed to improve the quality and reliability of clinical laboratory testing, begin taking effect on September 1. While previous regulations applied to laboratory facilities only, CLIA extends federal regulation to an estimated 130,000 physician's offices and 67,000 other testing sites, including pharmacies, nursing homes, home health agencies, hospices, rural clinics, and mobile and walk-in screening programs.

An independent study has estimated that the new regulation will cost upwards of $400 million in the first year alone.

If you have questions about how CLIA applies to your practice, call the CLIA hotline at 410-966-6802, or write HCFA CLIA Program, PO Box 26687, Baltimore, MD 21207-9487.

NORTH CAROLINA SALES TAX UPDATE

North Carolina imposes a sales tax on retail merchants. The primary purpose of the sales tax is to generate revenue for the State. Although the tax is imposed upon the retailer, it is designed to be passed on to the consumer. Currently, the general state sales tax rate is 4% of the retailer's net taxable sales. Local government entities also may impose a sales tax.

The sales tax is collected from the retailer, and the retailer must keep and preserve suitable records necessary to determine the amount of the sales tax for which the retailer is liable. Every retailer must retain for a period of 3 years all invoices of goods, wares and merchandise purchased for resale.

Pharmacies are retailers; therefore, they are subject to the sales tax. However, pharmacists should be aware of specific exemptions from the sales tax.

Medicines and Drugs

Sales of drugs or medicines on written prescription of a physician or dentist are exempt from state and local sales tax. Insulin is exempt from tax whether or not sold on prescription. Sales of drugs or medicines pursuant to a physician's or dentist's telephone (oral) prescription are exempt from sales tax provided the prescription is reduced to writing, signed by the pharmacist and filed in the same manner as a written prescription. The term "medicines and drugs" include tonics for internal use, vitamins, ointments, liniments, and antiseptics, anesthetics, serums and other remedies having preventative or curative properties in medical treatment. Pharmacists making sales of medicines or drugs pursuant to prescriptions must keep sales records which will clearly segregate such prescription sales. Sales of medicines or drugs not made pursuant to physicians' or dentists' prescriptions are subject to state and local sales tax.

Orthopedic Appliances

Sales of crutches, artificial limbs, artificial eyes, hearing aids, false teeth, and eyeglasses ground on prescription of physicians, pulmonary respirators sold on prescription of physicians, and other orthopedic appliances to be worn on the person of the owner or user, are exempt from state and local sales tax. Examples of tax exempt orthopedic appliances include: abdominal belts, cervical braces, clavicle splints, crutch tips, dorsolumbar supports, elastic anklets, elastic arch binders, elastic arch braces, elastic bandages, elastic hose, elastic wrist bands, head halters, invalid walkers, lumbosacral supports, maternity supports, postoperative supports, rib splints, sacroiliac supports, shoulder braces, spinal braces, stryker frames, suspensories, traction devices, trusses, walking canes, wheel chairs, cervical neck collars, leg braces, and ostomy bags, disks, tubes and belts. Ostomy supplies such as cements, removers, powders and germicides are subject to state and local sales tax.

Cathleen M. Plaut, J.D.

The following items are not exempt from sales tax unless sold pursuant to a written prescription: athletic supporters, foot cushions, bunion protectors or reducers, heel cushions, shoe insoles, toe flexes, walk strate pads, heating pads, heat lamps, oxygen regulators, oxygen tents and vaporizers. Pharmacists making sales of therapeutic, prosthetic, or artificial devices pursuant to written prescriptions must keep sale records which clearly segregate such prescription sales.

Cathleen M. Plaut, J.D, is an associate with Bailey & Dixon, Raleigh law firm.

ACROSS THE STATE

This column features news briefs about people, places and events related to pharmacy in North Carolina, and also about North Carolina pharmacists and other friends of pharmacy who must be out of the Tar Heel State for one reason or another. The NCPhA staff and The Journal's Editorial Advisory Board welcome and solicit your contributions to this column. Photos (black and white, preferably) are also welcome. Send us your news!!

The recently formed Davidson County Pharmaceutical Association met Sunday night, May 3, 1992 at the Days Inn Restaurant in Thomasville. The featured speaker was **J. Frank Burton, R.Ph.**, who presented a program on "Insulin Update." The meeting was sponsored by Mike Brown of Novo Nordisk Pharmaceuticals.

Congratulations to **Celeste M. Lindley**, Durham, who was recently named one of seventeen Fellows of the American College of Clinical Pharmacy. Lindley will be recognized during a special ceremony at the ACCP 1992 Annual Meeting. Recognition as a Fellow is awarded to ACCP members who have demonstrated a sustained level of excellence in clinical pharmacy practice and/or research.

Joe Whitehead was recognized at the American College of Apothecaries Midyear meeting in New Orleans by both ACA and NARD. Whitehead was recognized for his commitment to community pharmacy practice, pharmacy education and research during his career at Burroughs Wellcome Co. William L. Scharringhausen, president of NARD and Evelyn D. Timmons, past-president of ACA each presented Whitehead with a plaque.

Lucius Cooke, Mooresville, died Monday, May 18, 1992, following an automobile accident. A native of South Carolina, Cooke graduated from the University of South Carolina School of Pharmacy and served in World War II prior to entering pharmacy school. He was the owner-pharmacist of Cooke Pharmacy in Mooresville for 14 years. He sold an interest in his store in 1990 to Donnie Bowers.

Dan Grier McCrimmon, Pittsboro, died Saturday, May 30, 1992. He was 71 years old. A native of Carthage, McCrimmon graduated from the UNC School of Pharmacy in 1942 and operated a store in Robbins until he came to Pittsboro and went into business with his father in 1950. McCrimmon and his son Dan McCrimmon Jr. operated the family pharmacy, McCrimmon Drug in Pittsboro.

Congratuations to **Lisa** and Ed Grimes, Cary, on the birth of their first son Collin Hunter, born Memorial Day, May 25, 1992. Hunter appeared weighing 7 lbs. 8 oz., and standing 20 1/2 inches tall. Mother Lisa is Director of Professional Relations with Glaxo Inc.

Belated congratulations to **Patsy Millar Myers** (UNC '79) and Marti Myers on the birth of their first child, Joshua Millar Myers, on October 11, 1991. Patsy is pursuing a Master of Science Degree in Human Nutrition at UNC-G, while residing in Winston Salem.

Howard Glazer, Director of the Pharmacy Education Program at the Charlotte AHEC, has been named a recipient of the Merck Human Health Division Pharmacist Award. The award recognizes professional and civic achievements and Glazer was cited for his contributions to continued education and service to pharmacy.

Ken Burleson, Granite Falls, was named grand prize winner of the Rugby Laboratories Miata Sweepstakes. The grand prize (surprise) is a 1992 Mazda Miata.

Michael and **Elizabeth Downing**, White Lake, announce the birth of their second son, Zebulon Barrett, born April 30, 1992. He weighed 10 pounds, 10 ounces. Both Michael (1982) and Elizabeth (1979) are graduates of the UNC School of Pharmacy. Michael is employed by Wal-Mart and Elizabeth is a relief pharmacist at various retail pharmacies.

Detlef and **Kathryn Krimminger Badorrek**, Clemmons, announce the birth of a daughter, Julia Rae, on April 23, 1992. Kathryn is a 1984 graduate of the UNC School of Pharmacy.

DICKINSON'S PHARMACY

YOUR WINDOW OF OPPORTUNITY

Never have pharmacists had a better chance to seize control than they have in this extraordinary election season. It's a window of opportunity that may not be open long, or again.

The key is the national health debate, which this time is much more than political clap-trap.

This time, literally everybody is talking and worrying about it.

That fact is every pharmacist's cue to step forward and throw light into the tangled thicket of self-serving rhetoric that's confusing everybody.

Pharmacists have a simple message to get across to the public, and hundreds of opportunities each day to do it: Support the health plan that guarantees to keep the neighborhood pharmacies open—that is, the plan that guarantees freedom of choice of provider.

Patients will more easily see the pharmacy as an important asset to the community.

Since few of the options being touted by candidates and special interest groups will likely do this, it's up to the pharmacist to keep this simple message from getting lost, through posters and signs, bagstuffers, local media ads, etc.

But like a lot of simple messages, this one needs some not-so-simple support, since pharmacy as a whole has done such a bad job over the years in demonstrating why a personal pharmacy is important.

This is where the "opportunity" part comes in. Nobody promised you a rose garden. Opportunities take work to come into full bloom.

As all the political hype about health care heats up, pharmacists can be demonstrating their one-on-one importance as neighborhood health resources.

They can do this by seizing all opportunities to counsel, engaging in conversations about all aspects of health care, establishing a library/information center (PDR, USP-DI, health news clips, pharmacy literature) in a conspicuous corner, placing appropriate health messages throughout the store, and promoting aggressively in the community through print and air media, direct mail and cooperative displays in other health professionals' offices.

That's the hard part, of course. But nothing good ever came easy.

Signs that explain pharmacy pricing structures, showing manufacturer price increases and dispensing fee freezes, and comparing these to insurance company administrative costs (as high as 40% of premiums), can help patrons understand whose side you're on, and why.

Communications techniques shown in NARD's excellent free manual, *Ideas That Work*, can be used to great effect.

Try to engage local candidates in a debate, with the help of some patients you have helped motivate. The local news media will be interested in covering your call to debate, and this will provid additional pressure on the candidate to agree.

When Waverly, Tennessee, pharmacist Bob Phelan got a positive written reply from his state's Senator Jim Sasser on the discriminatory pricing issue, he bought a half-page ad in a local paper to display it, along with his question. "What do you think?"

The local response from supportive readers deluged Phelan for days and made him something of a celebrity, as well as an authority on health issues.

As recognition grows for your role as your community's local protagonist for better health care, the simple message of supporting the freedom of choice option in any proposed health plan will make more and more sense.

Patients will more easily see the pharmacy as an important asset to the community. Anything that even seems to threaten it will tend to be rejected.

Pharmacy's audience for this effort is vast and unusually attentive now. The window of opportunity gapes wide.

This can be pharmacy's cue to take control of its own destiny at last.

This feature is written and presented by Jim Dickinson, on a grant from "Dickinson's Pharmacy–The Independent Voice, a professionally stimulating, practical eight–page monthly newsletter. Annual subscription fee is $45.00. For more information or to order a subscription write: Ferdic, Inc. , P.O. Box 367, Las Cruces, NM 88004–0367

IMPORTANT TAX NOTICE

TO: Drug Manufacturers, Distributors or Retail Drug Stores

Recent Legislative Change:

Effective August 1, 1992, G.S. 105-164.13 was amended by adding a new subsection (13a) which exempts from sales or use tax legend or non–legend drugs donated to a non-profit organization to be used for charitable purposes. The term "legend" relates to drugs or medicines that normally may be dispensed only pursuant to a prescription. Any drug manufacturer or distributor or retail store that donates such medicines will be required to maintain adequate records to support the claim for exemption.

from N.C. Department of Revenue
Sales and Use Tax Division
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Raleigh NC 27640-2500

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CORRESPONDENCE COURSE

ADVISING CONSUMERS ON OTC HEMORRHOIDAL REMEDIES: AN UPDATE

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Goals

The goals of this lesson are to summarize FDA regulations governing OTC hemorrhoidal products, and present important information to insure that consumers use these products correctly.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. *demonstrate an understanding of important anatomical structures and physiologic events associated with hemorrhoids;*
2. *select safe and effective ingredients for self-therapy of hemorrhoids;*
3. *identify OTC hemorrhoidal products and identify pharmacologic and toxicologic actions, warnings and precautions associated with their ingredients; and*
4. *choose from a list informationto convey to consumers to insure that self-therapy of hemorrhoids will be maximized.*

FDA promulgated its final rule (monograph) in 1990 which defined the conditions under which anorectal drug products are generally recognized as safe and effective for self-therapy. This completed more than a decade of study and intensive review of drugs used to treat these prevalent, yet rarely discussed, conditions. This article summarizes those regulations.

Background

Anorectal disorders occur in the lower portion of the intestinal tract and interfere with its normal function and/or sensation. The most common disorder is hemorrhoids. Anorectal medication provides relief from discomfort in the perianal area, anal canal and/or lower rectum.

Hemorrhoids are among the most prevalent conditions for which pharmacists are asked to provide advice on product selection. It is reported that one-half of all Americans over age

Table 1

Definitions Relating to OTC Anorectal/Hemorrhoidal Products

Analgesic, Anesthetic Drug. A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors

Anorectal Drug. A drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or lower rectal areas

Antipruritic Drug. A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors

Astringent Drug. A drug that is applied topically to the skin or mucous membranes for a local and limited protein coagulant effect

External Use. Topical application of an anorectal drug product to the skin of the perianal area and/or the skin of the anal canal

Intrarectal Use. Topical application of an anorectal drug product to the mucous membrane of the rectum

Keratolytic Drug. A drug that causes desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis

Local Anesthetic Drug. A drug that produces local disappearance of pain, burning, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations

Protectant Drug. A drug that provides a physical barrier, forming a protective coating over skin or mucous membranes

Vasoconstrictor. A drug that causes temporary constriction of blood vessels

50 have suffered from hemorrhoids. It is also estimated that one-third of all households in the U.S. have at least one victim of hemorrhoids.

The exact cause of hemorrhoids has not been determined. They are unique to humans, rarely occurring in other animals. An upright posture is a major contributory factor. Occupations that involve standing for prolonged periods also contribute to their development. Other factors include the relatively low fiber content of the American diet, as compared to other cultures. This leads to harder, less bulky stools. Decreased physical activity lessens the tone of muscles in and around the anus. Pregnancy exerts a significant pressure on the anal region. And overuse (abuse) of stimulant laxatives causes excessive straining of the anal sphincter during bowel movements.

Understanding the anatomy of the rectal area is critical to comprehending what hemorrhoids are, and how drugs act. Sites of concern are the perianal area, anus and rectum.

The **perianal area** consists of skin immediately surrounding the anal sphincter and extending outward in the crease of the buttocks. It contains pain receptors, which makes it unique to the three regions discussed. The anus and rectum have pressure receptors but no nerve endings to sense pain. This is of great importance when considering the usefulness of local anesthetics. Unlike the skin in most areas of the body, perianal tissue is constantly moist and occluded.

The **anus** is the point where external skin changes composition to become the mucous membrane of the rectum. Its major function is, through cellular composition and sphincters, to guard against entry of foreign substances.

The anus has two sphincters: internal and external. The internal sphincter is involuntary and responds to defecation impulses from the autonomic nervous system when stimulated by the pressure of collected residue within the rectum. The external sphincter is under voluntary control.

Anterior to the anus, the **rectum** is the most distal portion of the GI tract. It extends outward for 12-15 cm from the sigmoid area of the large intestine to the anal sphincter. The rectum is lined with mucous membrane and contains pressure receptors that allow the body to perceive the need to evacuate accumulated feces. Its major function is to serve as a collection chamber.

Hemorrhoids

Hemorrhoids are unusually large conglomerates of blood vessels, supporting tissue, and overlying mucous membranes or skin of the anorectal area. A predisposing factor is that the rectal mucous membrane, like those in other areas of the body, contains a rich vasculature. Veins are most important to this discussion because some drain into the portal circulation which leads directly to the liver, while others drain into the general circulation, bypassing the liver. Drugs absorbed into the peripheral circulation distribute throughout the body without being first metabolized in the liver. Therefore, there is a greater chance for systemic side effects from drugs applied intrarectally.

A professional development program made possible by an educational grant from

SEARLE

Veins of the portal system are also important when discussing the cause of hemorrhoids because they do not contain valves, which are present in other veins. They are, therefore, incapable of preventing backflow and pooling of venous blood into the rectal area. Thus, the gravitation of blood resulting from upright stance contributes to its pooling in the hemorrhoidal veins. This increases pressure on the anorectal tissue. When pressure is sufficiently increased, such as during pregnancy and with straining at stool, these blood vessels enlarge. This can cause inflammation of the surrounding tissue and result in hemorrhoids, with itching, burning and pain.

Swelling of hemorrhoids is caused by enlargement of cells in the anorectal tissue due to accumulation of excess fluids in the hemorrhoidal veins. The area can be further enlarged by inflammation caused by trauma of wiping after a bowel movement, or irritation from improperly removed fecal material.

Self-Treatable Hemorrhoidal Symptoms

Hemorrhoids that are amenable to self-treatment are mild and self-limiting, and should clear with or without medication. There is nothing available OTC or by prescription to "cure" hemorrhoids. The goal of self-medication is to alleviate symptoms, which FDA describes as burning, discomfort, inflammation, irritation, itching, pain, soreness and/or swelling.

Advanced cases lead to bleeding (over and above minor bleeding that occurs due to wiping), protrusion of a large tissue mass out of the anal sphincter, and inappropriate seepage of feces. These conditions are not self-treatable and require physician supervision. Specific definitions of drugs used to treat hemorrhoids are listed in Table 1.

Ingredients

FDA differentiates between drugs for external use to the perianal area and those that could be introduced intrarectally. Since pain receptors are located in the perianal area, antipruritic agents, keratolytics and local anesthetics are effective there, but not within the rectum. Some astringents, protectants and vasoconstrictors may provide beneficial effects both externally and intrarectally. Approved ingredients are listed on the next page in Table 2.

Antipruritics. These are also referred to as analgesics and anesthetics. Some members of this group were originally classified as counterirritants, a term FDA rejected. Most were found to be either unsafe, ineffective or both. Their mechanism of action is felt to be due to stimulation of cold receptors in the perianal area. Since these are higher-level receptors than those for pain, the coolness sensation that results overrides and distracts from the discomfort and itching associated with anorectal/hemorrhoidal disorders.

Astringents. When applied to skin or mucous membrane, astringents decrease mucus and other cellular secretions, thereby alleviating local irritation and inflammation. By coagulating surface tissue proteins, they form a thin layer which may protect underlying tissue. Astringents can also aid in removal of surface tissue. They provide temporary relief from burning and itching, but not pain, associated with hemorrhoids.

Keratolytics. Keratolytics reduce itching. Their exact mechanism has not yet been determined, but they loosen and induce sloughing of surface cells in the perianal area.

Two keratolytics are approved for use in anorectal/hemorrhoidal products. Alcloxa is thought to act by breaking chemical bonds in the intercellular cement of stratum corneum, thus removing dead cells. It may stimulate new cellular growth as well. Resorcinol acts by altering keratin's structure, to increase its pliability and render it more easily removed.

Local Anesthetics. Local anesthetics block conduction of pain, burning and itching sensations to the brain. They are effective for external use on the perianal area, but not for intrarectal application.

Protestant. These agents provide a protective covering over skin and mucous membrane, thus preventing tissue irritation. Proctectant are approved for both external and intrarectal administration.

Vasoconstrictors. These constrict blood vessels. Since one sequelae of hemorrhoids is accumulation of blood in dilated veins, it is felt that vasoconstrictors have a beneficial role when applied to the anorectal area. Additionally, there is evidence that they exert local anesthetic action to alleviate itching.

Ephedrine sulfate and phenlephrine hydrochloride in aqueous solution are safe and effective for both external and intrarectal administration. Epinephrine in aqueous solution is suitable for external use, but will be rapidly inactivated in the alkaline pH within the rectum.

Table 2
Safe and Effective OTC Anorectal Product Ingredients

Antipruritics	
Camphor	0.1-3%
Juniper tar	1-5%
Menthol	0.1-1%
Astringents	
Calamine	5-25%
Hamamelis water	10-50%
Zinc oxide	5-25%
Keratolytics	
Alcloxa	0.2-2%
Resorcinol	1-3%
Local anesthetics	
Benzocaine	5-20%
Benzyl alcohol	1-4%
Dibucaine	0.25-1%
Dibucaine HCI	0.25-1%
Dyclonine HCI	0.5-1%
Lidocaine	2-5%
Pramoxine HCI	1%
Tetracaine	0.5-1%
Tetracaine HCI	0.5-1%
Protectants	
Aluminum hydroxide gel	
Cocoa butter	
Cod liver oil	
Glycerin	
Hard fat	
Kaolin	
Lanolin	
Mineral oil	
Petrolatum	
Shark liver oil	
Topical starch	
White petrolatum	
Vasoconstrictors	
Ephedrine sulfate	0.1-0.125%
Epinephrine	0.005-0.01%
Epinephrine HCI	0.005-0.01%
Phenylephrine HCI	0.25%

Safe But Unproved Effective Ingredients

Two components of anorectal products that were not included in the approved list of ingredients are hydrocortisone and live yeast cell derivatives. FDA continues to evaluate both ingredients.

Live yeast cell derivatives (ingredients in Preparation H and Wyanoids) have been used extensively for many years. It is claimed to be a wound healing agent which accelerates tissue repair to relieve symptoms. During its initial review of anorectal drug products, FDA advised drug manufacturers that two clinical studies demonstrating effectiveness in relief of hemorrhoidal symptoms were needed. Studies were undertaken and results submitted close to the deadline, but the FDA did not wish to hold up promulgation of its rule while it reviewed the data. Live yeast cell derivatives-containing products can remain on the market while FDA reviews the data.

Hydrocortisone represents a complex situation because it is under review by a number of different FDA panels, all of which have recommended it for self-therapy. Prescription products containing hydrocortisone are approved for relief of anorectal itching, and OTC external analgesic products can contain it for the temporary relief of anal itching. However, during FDA's review of anorectal drug products, a hearing was requested to switch hydrocortisone 1 percent to the OTC market, and another to recommend products containing hydrocortisone in combination with a local anesthetic for OTC sale. Since both hearings will take time, FDA did not want to delay promulgation of its rule on anorectal/hemorrhoidal products. So hydrocortisone-containing products, like those containing live yeast cell derivatives, may continue to be marketed and indicated for anal itching.

Indications

Permissible indications for OTC anorectal drug products are listed in Table 3. Using this table, manufacturers can develop specific indications for labeling their product. For example, the claim "helps relieve the local discomfort and itching associated with piles (hemorrhoids)" meets the monograph's requirements.

Additional indications can be added to the labeling depending on the product's ingredients. For example, products containing local anesthetics can state effectiveness for the symptoms burning, pain and/or soreness. For vasoconstrictors, the terms "temporarily reduces swelling associated with irritated hemorrhoidal tissue and other anorectal disorders" can be used, as well as "temporarily shrinks hemorrhoidal tissue."

For products containing a protectant, indications such as "temporarily forms a protective coating over inflamed tissues to help prevent drying of tissue," or "temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful" are allowable. Other allowable claims for these ingredients include "protecting irritated or inflamed areas" and "relieving burning skin irritations or discomfort."

Products containing camphor, menthol or juniper tar can list "for the temporary relief of pain and/or burning," "can help distract from pain," and/or "may provide a cooling sensation." Table 4 summarizes approved indications.

Warnings

Several warnings must be included on product labels. All must warn that if the condition worsens or does not improve within seven days, to consult a physician. Also, the following must be on the label: the recommended daily dosage should not be exceeded, and in

Table 3

Permitted Indication for OTC Anorectal Drug Products

1.	(a) For the temporary relief of (b) Gives temporary relief of (c) Helps relieve the
2.	(a) local (b) anorectal
3.	(a) discomfort (b) itching
4.	(a) in the perianal area (b) associated with
5.	(a) hemorrhoids (b) anorectal disorders (c) inflamed hemorrhoidal tissues (d) anorectal inflammation (e) hemorrhoidal tissues (f) piles (hemorrhoids)

Table 4

Guide to Hemorrhoidal Therapy
Based on Approved Indications for OTC Anorectal Drug Products

	Burning	Discomfort	Irritation	Itching	Pain	Soreness	Swelling
Analgesic, Anesthetic, Antipruritic	Yes	Yes	No	Yes	Yes	Yes	No
Astringent	Yes	Yes	Yes	Yes	No	No	No
Keratolytic	No	Yes	No	Yes	No	No	No
Local anesthetic	Yes	Yes	No	Yes	Yes	Yes	No
Protectant	Yes	Yes	Yes	Yes	No	No	No
Vasoconstrictor	No	Yes	Yes	Yes	No	No	Yes

case of bleeding, to consult a physician promptly.

Labels of products intended for external use must warn consumers not to put them into the rectum. For those intended for intrarectal application, the user must be warned not to use the applicator if it causes additional pain when introduced into the rectum. Instead, they should call a physician promptly.

Additional warnings are required for products containing several approved ingredients. Those with a local anesthetic, menthol or resorcinol, must warn: "Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor."

Products containing resorcinol must warn against use on open wounds near the anus. Those with aluminum hydroxide gel or kaolin must advise consumers to remove any greasy ointment before using the product because they interfere with its ability to adhere properly to the skin.

Products containing a vasoconstrictor must contain the same warnings as required on OTC nasal decongestants, appetite appeasers and bronchodilators: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination due to enlargement of the prostate gland, unless directed by a doctor," and "DRUG INTERACTION PRECAUTION. Do not use this product if your are presently taking a prescription drug for high blood pressure or depression without first consulting your doctor."

None of these effects are of consequence in a normal person, nor are they strict contraindications for patients with the diseases listed in the warning. The concept is that the potential for adverse effects exists, and a physician, not the patient, should decide whether use of the drug is safe.

Counseling Consumers

Pharmacists can play a major role in assisting consumers in selecting OTC hemorrhoidal remedies. A barrier to good communication can occur when consumers are too embarrassed to openly discuss their problem. Therefore, it is important to listen carefully to what the affected consumer describes in order to recommend the best product.

Consumers should understand that self-treatable hemorrhoidal symptoms should clear in a few days, and that continued self-medication can mask more serious medical conditions. The goal of treatment is to relieve symptoms while healing occurs spontaneously. Self-treatment with OTC products and other measures can help insure increased patient comfort during this period.

Consumers should be advised to wash the anorectal area with mild soap and warm water and to pat (not wipe) the area dry before applying a product. Alternatively, they can use one of the OTC anal cleansing pads such as Tucks or Gentz.

Other ancillary measures that can help alleviate symptoms and occurrence of hemorrhoids include increasing fluid intake and the amount of fiber in the diet. Avoiding straining during defecation is helpful, along with avoiding lifting heavy objects.

Special instructions are necessary to use a rectal applicator (Pile pipe). Consumers should attach the plastic applicator to the open tube, lubricate it well, then gently insert it into the rectum. If it causes pain, they should withdraw it and contact a physician. If there is no pain, they should squeeze the tube to deliver the product, remove the applicator from the rectum, wash it thoroughly in hot soapy water, then replace the cap onto the tube.

Suppositories are no longer considered an efficient means to deliver medication for hemorrhoidal symptoms, but they can remain on the market. If patients prefer their use, they should remove the wrapper before use and moisten the suppository into the rectum slowly, with mild pressure. If the suppository is too soft to insert, it can be held under cold water for a couple of minutes or refrigerated for 30 minutes.

As with other OTC products for which FDA has issued its final rule, pharmacists can use the information to properly counsel consumers on their safe and effective use.

CORRESPONDENCE COURSE QUIZ

Hemorrhoidal Remedies

1. OTC hemorrhoidal remedies containing which of the following ingredients are permitted to make the claim "temporarily shrinks hemorrhoidal tissue?"

a. Astringents
b. Keratolytics
c. Local anesthetics
d. Vasoconstrictors

2. All of the following are predisposing factors to development of hemorrhoids EXCEPT:

a. overuse of stimulant laxatives
b. decreased physical activity
c. a high fiber diet
d. occupations that involve standing for prolonged periods

3. FDA rejected use of which of the following terms as it relates to safe and effective ingredients in OTC hemorrhoidal remedies?

a. Analgesic
b. Anesthetic
c. Antipruritic
d. Counterirritant

4. Alcloxa is classified as a/an:

a. astringent
b. keratolytic
c. local anesthetic
d. vasoconstrictor

5. All of the following ingredients are effective in alleviating symptoms of hemorrhoids when applied both externally and intrarectally EXCEPT:

a. astringents
b. local anesthetics
c. protectants
d. vasoconstrictors

6. FDA's definition of a drug that causes desquamation and debridement of sloughing of surface cells of the epidermis best describes a/an:

a. astringent
b. keratolytic
c. local anesthetic
d. vasoconstrictor

7. Which of the following is a true statement?
a. Hemorrhoids affect most species of animals.
b. The perianal tissue begins at the anal sphincter and extends inward to the large intestine.
c. The perianal tissue contains pain receptors, but the anal and rectal tissue do not.
d. Resorcinol breaks chemical bonds in intercellular cement of the stratum corneum.

8. The warning "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes or difficult urination due to enlargement of the prostate unless directed by a doctor" must appear on the labels of OTC hemorrhoidal remedies containing which of the following ingredients?
a. Astringents
b. Keratolytics
c. Local anesthetics
d. Vasoconstrictors

9. Which of the following factors is most important to development of hemorrhoids as it relates to the veins in the portal system located in the rectal mucous membranes?
a. They do not contain an intimal lining.
b. There are so few that they are overworked.
c. They do not contain valves.
d. They contain pain receptors which aggravate hemorrhoidal irritation.

10. Which of the following ingredients in OTC hemorrhoidal remedies acts by coagulating surface tissue protein to form a thin layer which may protect underlying tissue?
a. Hamamelis water
b. Juniper tar
c. Dibucaine hydrochloride
d. Ephedrine sulfate

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1992-1993 NCPhA President Henry L. Smith

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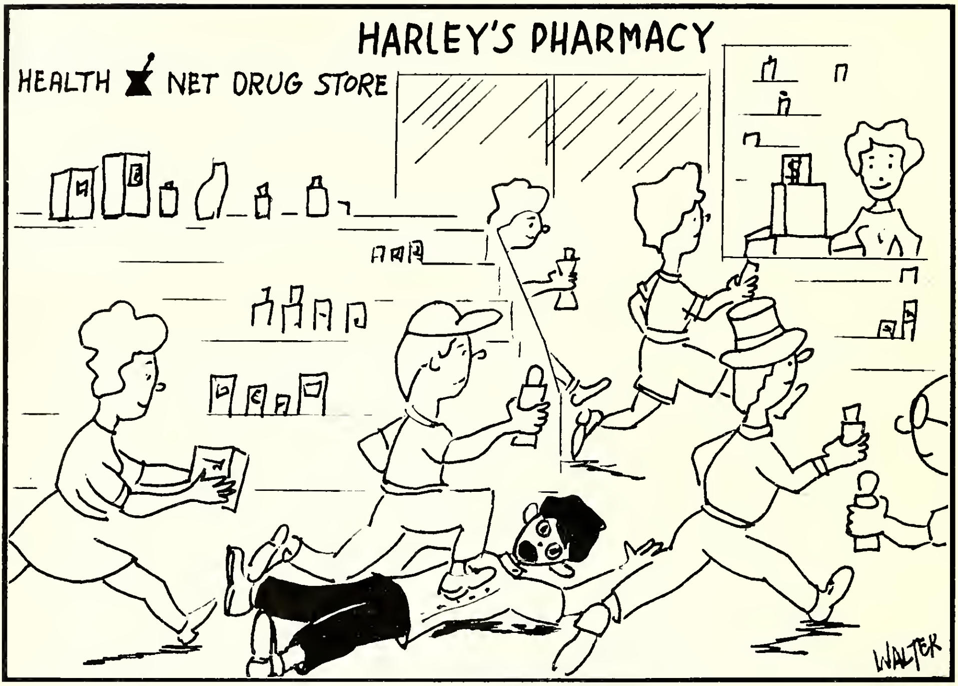

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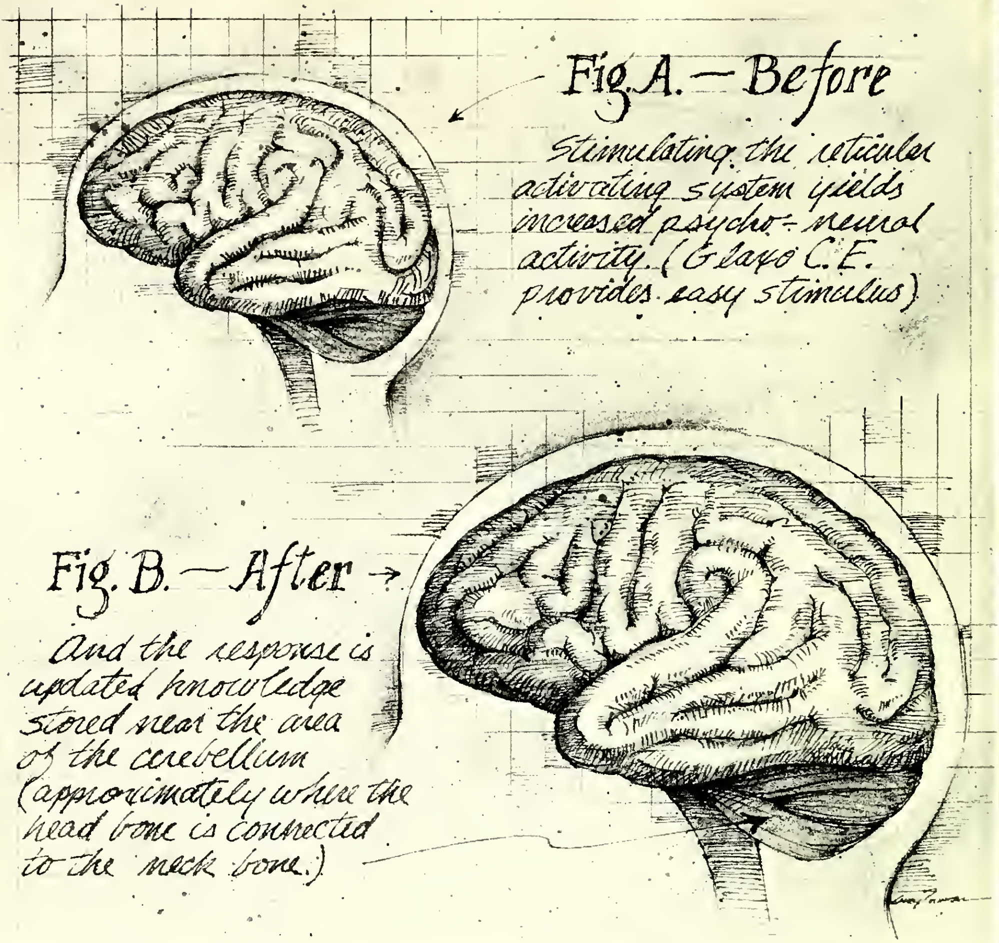
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1. *Diabetes Surveillance, 1980-1987.* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

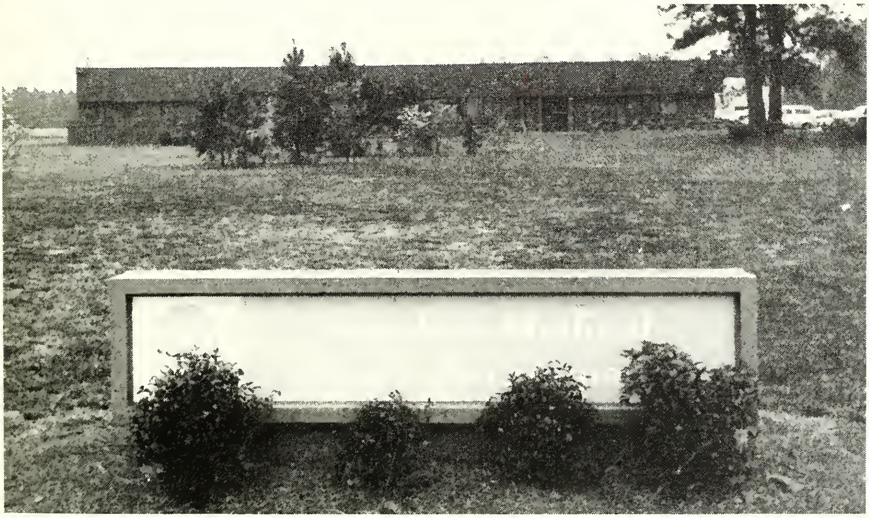
CAROLINA MEDICAL PRODUCTS

Carolina Medical Products Company, a 15,000 square feet pharmaceutical manufacturing company located in Farmville, was founded by and is presently operated by Dr. Jim Olson, president, and Henry Smith, vice-president. Dr. Olson holds a Ph.D. in pharmacy manufacturing from the University of Minnesota and joined the faculty at the UNC School of Pharmacy in 1969. He remained at UNC until the company was officially established in 1982. Smith is a 1967 graduate of Campbell University with a degree in chemistry and a 1972 graduate of the UNC School of Pharmacy. He also worked in the drug manufacturing department from 1972 until the company opened in 1982. Smith is the current president of the NCPhA.

The idea for the company surfaced while both Olson and Smith were working in the drug manufacturing department at the UNC School of Pharmacy from 1972 through 1982. In 1982, they moved the manufacturing facilities to the basement of Smith's home before soon relocating to a building on main street in Carrboro. This move marked the hiring of the first official employee. They talked proudly about the advances of the company when remembering that the first filling machine was a tea pitcher. They also joked about rolling the barrels of sorbitol down the hill in order to get them into the basement. As the company began to expand, and demand for their products increased, physical space began to be a problem again, so the facility in Farmville was constructed and opened in February 1986. Since this time, business has continued to grow and plans are being made to double the present size of the facility beginning in June.

Computerization of the entire company is going to occur within the next few months, which is another indication of the advancements of the company. Currently, the company has nineteen employees. Three are registered pharmacists, one is a Ph.D., and 15 are local workers. The company also hires temporary employees to fill shortages in the work force.

Carolina Medical Products Company works to make and distribute prescription, over-the-counter, cosmetic and repackaged products to hospital, retail and government agencies



Carolina Medical Products is located in Pitt County near Farmville.

across North Carolina, the United States and various other locations throughout the world. They distribute these products through UPS and other common carriers to wholesalers, as well as to their direct accounts. Smith stated that the company is not a "generic house, but a specialty company." They work to develop products that are too small for a larger company, i.e. Burroughs–Wellcome, to make but that are larger than what a hospital/retail pharmacy can produce. They receive their ideas for products by surveying hospitals and retail outlets to discover products that people are making in large quantities. Then a follow-up can be made by attending different types of shows to verify these needs and find common products among different areas. It is also necessary to look at the national sales potential to see if the product will be a success. Once these things have been determined, a decision is made whether or not to proceed with manufacturing. Also, they receive manufacturing ideas from people who call them to ask if CMP will make a specialty product for them.

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by James A. Boyd, Pharm.D., M.B.A.
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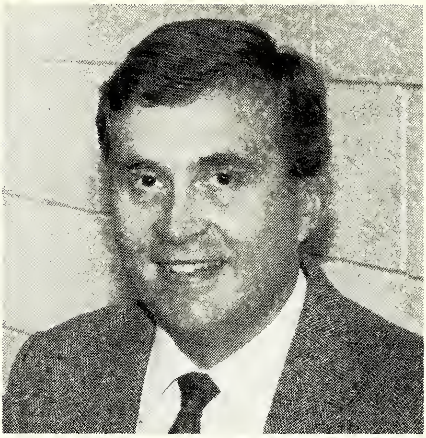

James A. Boyd

WHEN DOES COMPOUNDING BECOME MANUFACTURING?

Legal definitions of compounding and manufacturing are distinctly different, although from a practical point of view, the pharmacist may unknowingly cross over the boundary. The licensing, inspections, and recordkeeping requirements for manufacturing are also distinctly different than the requirements for compounding. Some pharmacists have developed specialty practices in the area of compounding prescriptions and over-the-counter (OTC) products. The practice of compounding includes, but is not limited to, the extemporaneous formulation of ointments, creams, elixirs, and suppositories. Other areas include compounding radioactive pharmaceuticals for nuclear medicine, ophthalmics, hyperalimentation, and other parenteral products, and formulating pediatric and geriatric dosage forms.

Manufacturing is regulated by the Food and Drug Administration (FDA) and is defined by the Food, Drug and Cosmetic Act (FDCA). Organizations in the "manufacturing" business must register as a manufacturer with the FDA. Manufacturers are subject to FDA inspections, and must adhere to the FDA's Current Good Manufacturing Practices (CGMP). If the manufacturer engages in the controlled substance business, he must also license the operation as a manufacturer with the Drug Enforcement Administration (DEA). (See the Controlled Substance Act for specific requirements for manufacturers.)

Compounding, on the other hand, is an activity which is regulated by the Board of Pharmacy of each state. Many states have adopted compounding in the definition of the practice of pharmacy, and have defined compounding. The confusion between compounding and manufacturing arises in part from the regulatory aspects creating a "chasm or overlap" in between state and federal definitions. Compounding is state regulated, while manufacturing is federally regulated. Until recently, FDA's position (10 years old) stated that prescriptions compounded extemporaneously for a specific patient is "compounding," while prescriptions compounded in "anticipation" of a prescription may fall into the manufacturing category. One problem with this approach is that pharmacists have historically prepared products in anticipation of a prescription. Stock solutions and compounds have been prepared in anticipation of a prescription in almost all practices of pharmacy. Other examples include: medications prepared for physician office use and the partial preparation of medications in advance.

Legal decisions have not only been based upon the written law, but also upon the standards of practice, case precedent, and the spirit or intent of the law. For example, in a court case against Cedar North Towers Pharmacy, the court noted characteristics which would help classify an activity as compounding or manufacturing. The following criteria have been a practical guide for pharmacists. The six factors cited to identify the questioned activity as manufacturing or compounding include:

1. whether particular drugs are being compounded on a regular basis as opposed to periodic compounding of different drugs;

2. whether drugs are being compounded primarily for individual patient prescriptions as opposed to orders contemplating larger amounts for office use;

3. the geographic area of distribution;

4. whether any form of advertising or promotion is being utilized;

5. the percentage of gross income received for sales of particular compounded drugs; and

6. whether particular compounded drugs are being offered at wholesale prices. (Food Drug and Cosmetic LawReports, Sec 38.2000, 1978).

The practice of repackaging and relabeling medications may fall beyond the practice of pharmacy into the area of manufacturing, which requires FDA licensing and inspections, and compliance with the CGMP. The FDA gave three situations in pharmacy practice that should help identify the boundary of what is manufacturing.

1. If the pharmacy in hospital "A" repackages drug products for its own use as well as for that in hospitals "B" and "C."

2. If a pharmacy chain repackages and relabels quantities of drug products from the manufacturer's original commercial containers for shipment to the individual franchises of the chain; and

3. If similar repackaging and relabeling are conducted by individual pharmacists as members of an informal buying group. (43 Fed. Reg. 45028, 1978)

In March of 1992, the National Association of Boards of Pharmacy (NABP) in response to the Food and Drug Administration prepared draft definitions for compounding and manufacturing.

Compounding means the preparation, mixing, assembling, packaging, or labeling of a drug or device (i) as the result of a practitioner's Prescription Drug Order or initiative based on the pharmacist/patient/prescriber relationship in the course of professional practice, or (ii) for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs and devices in anticipation of Prescription Drug Orders based on routine, regularly observed patterns.

Manufacturing means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

Comment: Nothing in these definitions of compounding and manufacturing shall preclude a pharmacist from informing practitioners or patients of the ability to compound or availability of compounding services.

In summary, the boundary between compounding and manufacturing is hazy.

Editor's note. Please read the letter on the next page which was recently sent to all chief executive officers of the Joint Commision of Pharmacy Practitioners after a meeting with FDA Commissioner Dr. David A. Kessler.

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Mr. John A. Gans
Executive Vice-President
American Pharmaceutical Association

Dear Mr. Gans:

This is in response to your letter of July 6, 1992, concerning pharmacy compounding and the pharmacist's right and responsibility to compound prescriptions in support of physicians' desires and patients' special needs.

Let me assure you that the position of the Agency has not changed since my address to the Opening General Session of the 1992 Annual Meeting of the American Pharmaceutical Association. I stated then, and I restate now, that neither the Agency's compliance policy guide nor the Agency's enforcement efforts represent any intent by FDA to interfere with the extemporaneous compounding and manipulating of reasonable quantities of drugs by licensed pharmacists based on valid prescriptions written for individual patients by licensed practitioners.

> *...neither the Agency's compliance policy guide nor the Agency's enforcement efforts represent any intent by FDA to interfere with the extemporaneous compounding and manipulating of reasonable quantities of drugs by licensed pharmacists based on valid prescriptions written for individual patients by licensed practitioners.*

We will continue to work with state and local officials, the National Association of Boards of Pharmacy, and the Joint Commission of Pharmacy Practitioners (JCPP) to resolve, wherever possible, any issues that currently exist regarding the legitimate compounding of physicians' prescriptions versus drug manufacturing.

We apologize if the release of certain Agency documents has resulted in confusion in the pharmacy profession as to exactly what the Agency's policy is with regard to compounding. Some of these documents involved matters that were initiated prior to the issuance of the compliance policy guide. It has been and will continue to be our policy to generally defer to state and local officials for the regulation of the day-to-day practice of retail pharmacy and related activities. Mr. Ronald Chesemore, the lead Agency official for implementing the Agency's policy, will ensure that the field offices and center compliance officials' activities are properly coordinated.

While the Agency recognizes traditional compounding as performed by community pharmacists, we have significant concerns about commercial amounts of drugs being manufactured under the guise of "compounding." We believe that the vast majority of the pharmacy profession shares our concern. When necessary, we will take appropriate action against those few whose so-called "compounding" amounts to large-scale manufacturing and sale of what are unapproved new drugs of unknown safety and efficacy. As you know, some of these operations have their own detail persons, marketing consultants, and promotion departments. They buy unapproved drug substances in bulk quantities and manufacture products on a large scale. They operate like manufacturers or wholesalers, but without the stringent safety and quality controls of legitimate pharmaceutical companies.

The total number of firms that manufacture drugs under the guise of "pharmacy compounding" is far fewer than the number of pharmacies that exercise the art of traditional compounding. Unfortunately, it is these relatively few who have cast a pall over pharmacy compounding. As you know, Ron Chesemore and others within the Agency are working with the JCPP to describe the boundaries of compounding. It is not the intention of the Agency to stop or interfere with traditional compounding. We fully recognize the important role that pharmacists play in our health care system.

Thank you for writing to us and sharing your views. I look forward to your support in conveying the Agency's policy to your membership.

Sincerely yours,
David A. Kessler, M.D.
Commissioner of Food and Drugs

JACK WATTS RECEIVES BOWL OF HYGEIA AWARD

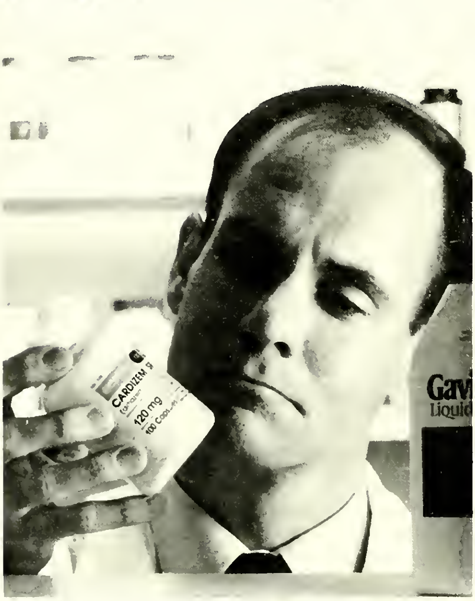
Jack Watts of Burlington has been honored by the North Carolina Pharmaceutical Association as its 1992 recipient of the "Bowl of Hygeia" Award for outstanding community service. Watts, Associate Director of Pharmacy at Greensboro AHEC, received the award on May 21, 1992, at the association's annual meeting in Pinehurst.

Making the presentation was Mr. Jeff Robertson of Wyeth-Ayerst Laboratories. Participating in the ceremony was Betty H. Dennis, president of the North Carolina Pharmaceutical Association.

Watts is active in his community where he is the chairman of the Burlington City School Board and a member of the Board of Directors of First Union Bank in Burlington. He has also served on the Board of Directors for Hospice of Alamance County and the Alamance Diabetic Association.

Watts is a past president of the North Carolina Pharmaceutical Association, and has served on the Executive Committee for four years. He was named Pharmacist of the Year in 1986. Watts is currently the Assistant Secretary Treasurer and past president of the Alamance Pharmaceutical Society and is President of the Board of Pharmacy and the Board of Trustees of Campbell University. He is a member of the American Society of Consultant Pharmacists, the Southeast Society of Hospital Pharmacists and the North Carolina Society of Hospital Pharmacists. Watts received his pharmacy degree from the University of South Carolina.

Established in 1958, the award is now presented annually by participating pharmaceutical associations in each of the United States, the District of Columbia, Puerto Rico and the 10 provinces of Canada.



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As you fill a prescription for that customer who's been doing business with you for years, it's nice to know that Marion Merrell Dow Inc. checks the quality of each and every product–before, during, and even after the manufacturing process.

As you go through each day, thankful for your business and your quality of life, it's nice to know that you can always depend on Marion Merrell Dow Inc. for quality of product.

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Life Membership in the NCPhA is obtained by one of two ways. First), the Executive Committee of the NCPhA may vote to bestow a Life Membership on a member for many reasons, such as exemplary service to Pharmacy for many years, etc., or Second) a member may purchase a life membership by making a one-time payment of ten times the current annual dues. In the case of a regular, in-state member, this would be one thousand dollars, or for a husband and wife who want a joint Life Membership, the cost is fifteen hundred dollars. Life members are insulated against future dues increases and never have the hassle of renewing their membershps. Call NCPhA for more information.

DICKINSON'S PHARMACY

WHAT IF THERE WERE NO PHARMACIES?

This isn't exactly a hypothetical question. Small, one-horse towns have been losing their only drugstore for many years, and now densely populated urban areas have been losing theirs, as well.

The reasons are varied. Population shifts can make marginally viable businesses not viable. Crime can force stores to close. Death or illness can shut down a pharmacy forever when another pharmacist willing to be an owner can't be found.

I'm not thinking of these factors when I pose the question, What if there were no pharmacies?

What If There Were No Pharmacies? (and all medicines came by mail?)

I'm thinking about "managed care" (more accurately, "managed cost") policies that, by their level of reimbursement and administrative complexity, logically — but unwittingly — invite the pharmacy owner to go into some other line of work.

Some might think that such policies concern only those directly involved — the payor and the payee. But pharmacists know that such policies would most powerfully impact the patient if they forced pharmacies to close.

So why shouldn't the patients be asked to consider the consequences of such policies? Our whole social system, from marketplace through government, is based on the law of supply and demand.

To the extent that "managed care" policymakers see pharmacies as being in inexhaustible supply, existing to be picked off as the pioneers once picked off buffalo and redwood trees without any thought for tomorrow, then patients, employers and politicians can hardly be blamed for assuming the same attitude.

Isn't it up to pharmacy to say, "Hey, we're hurting — and that could hurt you"?

Shouldn't those with the most at stake — patients who depend on being able to physically go to a pharmacy whenever the need arises — be asked to consider where they would be if there were no pharmacy to go to?

In other scenarios that are not so life-and-death, citizens have become sufficiently aroused to alter policies that were adverse to their interests.

Consider various threats to close a local school because of dwindling enrollments, close the bus depot, or the post office, or the newspaper recycling service, or a local park, or the police substation, or...

Sometimes, an apathetic citizenry will just shrug its collective shoulders and grumble a lot.

But, very often, it only takes one incendiary to organize them into an effective fight.

And so it might be in the case of pharmacy's collective fight to get a better deal from managed care.

The message below is intended to be copied, enlarged into a poster, and displayed in the pharmacy. It can also be made into a local direct mail flyer, a pharmacy bagstuffer, or a newspaper advertisement. Start winning the war of public opinion now!

What If There Were No Pharmacies? (and all medicines came by mail?)

Don't take it for granted that there will

always be retail pharmacies to go to when you need a prescription filled unexpectedly.

Insurance plans, Medicaid and other third parties are now shifting prescription coverage away from local pharmacies in the mistaken idea that this saves them money. Your prescriptions in the future could reach you only by mail.

Where would you go in an emergency? The nearest hospital, where there are long waits and disinterested service?

Who would you call for advice when you're doubtful about a drug effect? Your busy doctor, who is hardly a "second opinion" on drug effects and interactions?

Who would check your prescription against your other medications (prescribed perhaps by doctors) in case of a conflict? Somebody at an 800 number?

Who would your doctor call when he wants to modify your prescribed therapy based on your reactions to it? The same "somebody" — or somebody else? And what do they know?

What if you forgot to take your medicine with you on a trip? There would be no pharmacies anywhere!

Suppose the mailman brought the wrong medicine? It happens more than you think!

Don't take your local pharmacy for granted. Your local pharmacy is hands-on professional care, right where you can see it and get immediate assistance at any time.

Support this continued service to the neighborhood by opposing any move to send your prescriptions out of town to mail-order prescription processors.

FOR YOUR CONTINUING HEALTH AND SAFETY, LOCAL PHARMACIES ARE TOO VALUABLE TO LOSE!

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FOR PHARMACISTS

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THE PLACE: BEAVER RUN RESORT — BRECKENRIDGE, COLORADO

THE BEST: Room prices start at $115 per night (sleeps up to 4)
Selection of room/suite sizes ideal for families.
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Registration for the program is $300 per pharmacist.

REGISTRATION — includes 15 hours of Continuing Education, full breakfasts for four mornings, welcome reception and other planned functions. Limited space available.

Interested pharmacists please send a check for $100 to the Colorado Pharmacal Association, 770 Grant St., Suite 244, Denver, CO 80203 to hold your spot. Any questions please call Tom Gray Executive Director of CPhA at 303-861-0328. Other details available on request.

THIS PROGRAM SPONSORED BY
National Council of State Pharmacy Association Executives and The Colorado Pharmacal Association.

HIGHLIGHTS OF THE 112TH NCPHA ANNUAL CONVENTION AND AFFILIATED AUXILIARIES

Based on your response to the post convention survey, the 112th Annual Convention of the NCPhA and Affiliated Auxiliaries was rated a "five star" meeting. Over 470 pharmacists, family members, students, and industry representatives gathered in beautiful Pinehurst for the three day gala. Attendees enjoyed special continuing education workshops, sporting activities, awards sessions, dancing, and a magical exhibit program. If you weren't a part of this year's meeting, plan now to join us in 1993 in Atlantic Beach, May 23–26.

THANKS TO OUR CONVENTION CONTRIBUTORS AND SPONSORS

The following companies contributed greatly to the success of our 1992 Convention by donating prizes, providing funding for speakers, activities, and receptions. Please show your gratitude to the representatives of each of these companies and organizations.

(Special thanks to the Burroughs Wellcome Co., Glaxo Inc., and Owens Brockway for their generous sponsorship of the Golf Tournament held at world-famous Pinehurst # 2 and # 7 courses.)

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THANK YOU, 1992 CONVENTION EXHIBITORS

An integral part of the NCPhA Convention is the one-day Exhibit Program. Over 40 companies and organizations were represented at the function. This year's program featured a sumptious buffet, a strolling magician, and prize drawings throughout the evening. The grand prize–a free registration for the 1993 Convention in Atlantic Beach–was won by Dan Mantine of Frederick, MD. Much appreciation to Marion Merrell Dow for sponsoring the magician and the reception preceding the Exhibit Program. Exhibitor's fees help reduce the total cost of the Convention, so please let them know how much you appreciate their participation and support.

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Magician Bob Sheets mystified the audience with a performance in the exhibit hall.

photo by Qualex

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TMA Officers present a check for $2,500.00 to NCPhA Executive Director Al Mebane for the TMA Foundation Loan Fund. Left to right: Bill O'Quinn, Rudy Snow, Al Mebane and Bill Andrews. *Photo by Qualex*

KUDOS

Recipient of the Don Blanton Award, Joe Whitehead, with his wife Ina, *left*, and the stand-in presentor of the award Margaret Ramsey.

Jack Watts, recipient of the A.H. Robins Bowl of Hygeia Award, with his wife, Eloise.

Photos by Qualex

Members of the Executive Committee *from the left*, Keith Elmore; Rob Bizzell, President Elect; Pam Joyner; Rebecca Wheeler; Robert Worley; Betty Dennis, Past President; Henry Smith, President. Not pictured are Jimmy Jackson and Mickey Watts.

Kevin Almond, *left,* was presented the Distinguished Young Pharmacist Award by Marion Merrell Dow Representative Paul Harmina.

...AND MORE KUDOS

E.R. Squibb Past President's Award
Betty H. Dennis, Carrboro

Geigy Outstanding Service Award
Betty H. Dennis, Carrboro

McKesson Incoming President's Award
Henry L. Smith, Farmville

NARD Leadership Award
Henry L. Smith, Farmville

Pharmacy Award for Compensation Excellence (P.A.C.E.)
Kaiser Permanente
Burroughs Wellcome Co.
Yale New Haven Hospital

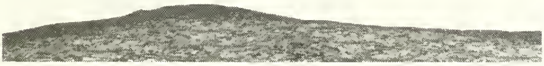
Inductees into the "50-Plus" Club
Thomas M. Holland, Mount Holly; John H. Brown, China Grove; Ruth M. Cox, Winston-Salem; Dan G. McCrimmon, Pittsboro; Jack W. McAdams, Burlington.

Photos by Qualex

Henry Smith, 1992-93 NCPhA President presents Betty Dennis with a past president's pin.

Ralph Ashworth, 1992 Pharmacist-of-the-Year with his wife, Daphne.

Reflections



WA Walk-A-Thon participants *front row, from left*, Rose Boyd, Jean Morse, *2nd row,* Daphne Ashworth, Ina Whitehead, Kay Rhoades, *3rd row*, Erie Cocolas, Betsy Mebane, Carolyn O'Quinn, *back row,* Mary Lou Worley, Dave Work, and Robert Worley.

WA President Suzan Maddox addresses the Association during the 2nd General Session.

photos by Qualex

1992-93 WA Officers: *from left*, Mrs. A.H. Mebane III, Coordinator; Mrs. Robert Worley, Advisor; Mrs. Suzan Maddox, Advisor; Mrs. David Moody Jr., Treasurer; Mrs. Fred Eckel, Corresponding Secretary; Mrs. William O'Quinn, President; Mrs. Henry Smith, 1st Vice President; Mrs. Jimmy Jackson, 2nd Vice President; Mrs. Robert Garrett, Recording Secretary; Mrs. Antoine Alachi, Parliamentarian; and Mrs. Larry Brown, Historian.

Frances Jones presents Ray Maness and Jack Watts, *not pictured*, with a medal for raising the most money for the Walk-A-Thon.

Following her presentation, Nancy Brinker, *left*, joins Vivia Creech for the WA luncheon.

WOMAN'S AUXILIARY 1992 CONVENTION REPORT

by Mrs. Suzan Maddox, 1991-92 President

The 65th annual convention of the Woman's Auxiliary of the NCPhA was held May 21-24, 1992 at the Pinehurst Resort and Country Club in Pinehurst, North Carolina. It is truly a beautiful country club surrounded by some of the world's finest golf courses. As always, the highlight of the convention was the chance to see friends, old and new, and enjoy spending time together. We all received "goody bags" donated by NC Mutual Wholesale Drug Company. We ALWAYS enjoy finding what surprises they have tucked inside.

A reception was held on Thursday evening to honor Dean Tom Miya on his retirement and also the presidents of the three groups. Our opening banquet speaker was Vicki Reid. She spoke from her book *What You See Is What You Get* on making a positive statement about yourself by the way you dress. Vicki brought the house down when she cut Al's tie from around his neck and threw it away!

Friday morning was the culmination of almost a year's preparation by the Lifesaver's Committee, especially Chairman Tracey Smith and Vivia Creech. Nancy Brinker, author of *The Race is Run One Step At a Time,* was the featured speaker for a joint session of all three groups. Nancy is a member of the President's National Cancer Advisory Board and the founder of the Susan G. Komen Foundation for Breast Cancer Research. She has raised over $11 million through this foundation. "Race for the Cure" fun runs are held all over the country. Women and men wear the name of a breast cancer victim as they run, and all the women that are breast cancer survivors wear pink sun visors. It is my genuine hope that we can participate in one of these races.

Ms. Brinker's talk was sponsored by Miles Pharmaceuticals, Merck, Smith-Kline Beecham, Burroughs-Wellcome Co., and ICI. Each of these companies has my heartfelt appreciation for the support they so generously gave us. From a personal viewpoint, Nancy Brinker was as sincere and kind as anyone I have ever known. Her dedication to her mission is awe-inspiring. I was thrilled to spend a few hours with her and to get to know this dynamic lady. Women and men were enriched by her sharing. (All money went to the Komen Foundation.) Glaxo sponsored the luncheon that followed, which included a videotaped personal message from Marilyn Quayle, wife of the Vice President of the United States. This was provided by ICI Pharmaceuticals. Mrs. Quayle spoke of the loss of her mother to breast cancer, and her concern that we as women be ever vigilant in protecting our health. Mrs. Quayle sent regrets that she could not be with us in person as we had hoped she would, but asked that we invite her back at another less hectic time. Later we had a choice of croquet with the hotel's pro, or a cooking demonstration with the chef. Both were enticing, so it was a hard decision! I chose cooking and got to decorate my own cake. I thought I showed real promise as long as the pastry chef stood right beside me. My children could not believe that I had made this gorgeous creation.

Friday evening we were treated to a dance sponsored by the TMA, with music by "Second Chance" of Durham. Always a fun evening…thanks TMA. We appreciate all you do for pharmacy in North Carolina, especially your significant contributions to the pharmacy student loan fund.

Bright and early Saturday morning found many of us up and out for a two mile trek around the golf course for our annual Walk-A-Thon. Each walker was given a t-shirt for his/her effort. Kendall Drug Company donated the shirts again this year. I have quite an assortment of these t-shirts from over the years and love to look back and remember each convention. I'm glad they have the date on them because that helps jog the old brain. More than $1500 was raised by the Walk-A-Thon. Medals went to Ray Massey of Durham and Jack Watts of Burlington for raising the most money.

Our other big fundraiser was the raffle of

$500 cash, won by Charles Creech of Oxford. A mini vacation at Tom Burgiss' Bed & Breakfast was won by Betty Jane Upchurch of Durham and a beautiful watercolor painting by Ruby Creech was won by Willis Whitehead of Siler City. Czarina Andrews of Burlington won a ceiling fan and Lee Werley of Chapel Hill a 6 inch TV. Dot Moose of Mt. Pleasant won some luggage, while Margaret Boyd of Mt. Olive won a grill. And Omni Grabs Jr. of King was the winner of a nice radio. About $1300 was raised through your effort in selling these tickets. This money helps the Woman's Auxiliary with service projects all over the state. For all of you that supported these fundraisers, we say **THANKS!!**

Jean Morse and Frances Jones have done a whale of a job as co-chairs of Ways and Means this year. In addition to the raffle and walk-a-thon, they had notecards, coat of arms plates, cross-stitch kits, and tin-punch boxes for sale. Ruby and Vivia Creech did the table decorations for our luncheons and they were lovely as well as unique. At the luncheon on Friday, the centerpieces were made with miniature golf clubs and balls to carry out the theme of Pinehurst's status as *Golfer's Heaven.*

Now you might think that a business session would be pretty dull, but not with the WA. We heard reports of all the things that were done this year, received greetings from the president of NCPhA, Betty Dennis, the first female president of this group and a real dream to work with this year; and TMA president, Junior Little, who is a new groom. Best of all were the wonderful door prizes we all won!! Erie Cocolas had been busy for months getting things donated by numerous companies. Our appreciation to all who contributed prizes.

Our Vial of Life project continues to have numerous requests; the Literacy Poster has gone nationwide and has been written up in "Wellcome Trends," a magazine published by the Burroughs-Wellcome Company. The Lifesavers project to promote women's health concerns has gotten underway with several members setting up groups to hear an American Cancer Society speaker discuss women's health; and the Mobile Mammogram Unit from Memorial Hospital in Chapel Hill has been on several visits to the Campbell University campus with full capacity usage, and monthly visits planned. Our membership has continued to expand under Peggy Jackson's attention as Membership Chairman, and a new local group has been formed in Buies Creek.

Following the luncheon, a meaningful installation ceremony was conducted by Rose Boyd, past president, of Kenly. Our luncheon and fashion show was sponsored by Burroughs-Wellcome. We are truly blessed to have so many bright and talented women on our Board for the coming year. Carolyn O'Quinn is going to be a fantastic president. Incidentally, her husband, Bill, is president of TMA for the coming year. If you have not gotten to know Carolyn yet, let me encourage you to because she is a very genuine person.

Speaking of Carolyn, she and the Hospitality Committee did a superb job with the hospitality room. I wish to thank all the ladies that contributed munchies and made us feel so welcome.

As always, the staff of the Institute had planned for every detail of the Convention. It all went off like clock-work. Tom Burgiss kept us on time and moved us along through our agenda. I have renewed respect for the planning that it takes to have a successful convention. Let me express all our thanks to Al, Betsy, Erie, Terri and Michelle for a job well done.

I would like to thank each of you for giving me the opportunity to be your president this year. I shall always treasure the lovely silver tray presented to me in recognition of my term as president. I am extremely proud of the Auxiliary and proud of the things we have been able to do by working together.

God bless you each and every one!

1991-92 NCPHA COMMITTEE REPORTS

Report of the Nominating Committee

The Nominating Committee of the North Carolina Pharmaceutical Association, in accordance with the Constitution and Bylaws, does hereby present the following slate of officers. Each person nominated on this slate has agreed to serve if elected. This slate, along with any nominations from the floor of the Annual Convention, will be submitted to the membership by mail ballot.

Those officers elected by a plurality of the votes received and counted will be installed in their respective office during the 1993 Annual Convention.

The candidates are:

For President Elect
Phillip F. Crouch, Asheville
Jimmy S. Jackson, Garner

Note:
Joseph A. Edwards Jr., Raleigh, was nominated from the floor for the office of President Elect and will appear on the mail ballot.

For Executive Committee Member
(Two persons to be elected to three-year terms)
Randy G. Ball, Wake Forest
Robert S. Beddingfield, Southern Pines
C. LeRoy Hill, Charlotte
Mary Ann Largen, Charlotte
John A. Mitchener III, Edenton
Thomas R. Thutt, Kinston

Members of the committee were: Chairman Henry L. Smith, *Farmville*, Sarah B. Cobb, *Southern Pines*, Steve L. Critz, *North Wilkesboro*, J.A. Hill, *Charlotte*, Pamela U. Joyner, *Morrisville*, Wallace E. Nelson, *Hertford*, Thomas R. Thutt, *Kinston.*

Editorial Note: Biographical sketches of these candidates will appear in the January issue of the Journal. At the same time, ballots will be circulated to the membership by mail.

Report of the Resolutions Committee

Resolutions Acted Upon at the 1992 Convention

RESOLUTION # 1

TO CHANGE BYLAWS ARTICLE VI, SECTION 3. QUORUM FOR MEETINGS

WHEREAS, the current bylaws state that fifty "members" constitutes a quorum, and

WHEREAS, the Association has five categories of "members" (active, life, student, honorary and associate) as defined in the Constitution, three of which are not eligible to vote (student, honorary and associate), and

WHEREAS, the business of the Association should be conducted by those members eligible to vote, and

WHEREAS, as currently stated, nonvoting members could be counted towards a quorum for meetings, and

WHEREAS, the Constitution and Bylaws Committee and the Executive Committee endorse this Resolution

RESOLVED, that all such references to quorum in the Bylaws be changed to "*members present and eligible to vote.*"

Action: *Adopted*

RESOLUTION #2

TO CHANGE BYLAWS ARTICLE IX. AMENDING THE BYLAWS

WHEREAS, as stated, propositions to change the Bylaws could be brought up as new business on the floor of the convention without review by any Association committee, and

WHEREAS, changes to the Constitution must be approved by the Constitution and Bylaws Committee and the Executive Committee before presentation for a vote, and

WHEREAS, changes to the Bylaws should be given adequate review and consideration, and

WHEREAS, the Constitution and Bylaws

Committee and the Executive Committee endorse this Resolution

RESOLVED, that Bylaws Article IX be reworded to state: "Every proposition to alter or amend these Bylaws shall be submitted in writing to the Constitution and Bylaws Committee and, if accepted, referred to the Executive Committee who shall submit it in writing at one business session of an annual meeting and shall be decided by ballot at a subsequent session when, upon receiving a vote of 2/3 of members present and eligible to vote, it shall become part of the Bylaws.

Action: *Adopted*

RESOLUTION #3
TO PROMOTE A THIRD CLASS OF DRUGS

WHEREAS, many "legend" drugs in the United States are "OTC" drugs elsewhere in the world, and

WHEREAS, many "legend" drugs in the United States will soon be coming off patent and/or may become eligible for "OTC" consideration, and

WHEREAS, many of these products have significant interaction probabilities with other drugs, and

WHEREAS, many countries outside the United States have a transitional or third class of drugs to provide improved patient care through timely counseling from pharmacists

RESOLVED, that the North Carolina Pharmaceutical Association in convention assembled this 24 day of May, 1992, endorse the creation of a third class of drugs in the United States by the Food and Drug Administration through appropriate congressional legislation.

Action: *Adopted*

RESOLUTION #4
TO INCREASE ANNUAL DUES

WHEREAS, the impact of State Government on the health professions in North Carolina continues to expand, and

WHEREAS, the General Assembly's actions in the past term concerning reimbursement of prescriptions for state employees evolved into an unwise and untimely position, and

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WHEREAS, the correction of this matter and its implication may take considerable effort over time

RESOLVED, that the North Carolina Pharmaceutical Association in convention assembled this 24 day of May, 1992, increase in the next fiscal year its annual dues by the sum of $10.00 for the purpose of improved lobbying of State Government and for staff development at the Institute of Pharmacy.

Action: *Adopted*

Report of the Constitution & Bylaws Committee

The Committee met at the Institute of Pharmacy on February 23, 1992. One item of old business, a Constitutional change, was carried over from the 1991 convention. The change is to delete "and continue to do so upon renewal of membership" from Article III, Section 1, Code of Professional Ethics. This change was presented at the 1991 annual meeting and will be voted on at the 1992 annual meeting.

The Committee will submit two Bylaws changes to the 1992 annual meeting with the approval of the Executive Committee. One change would redefine how a quorum is counted and the other would change the procedure for amending the Bylaws. *Refer to the Resolutions Committee Report for proposed Resolutions.*

The Committee discussed one other item of new business: clarification of the Bylaws regarding introduction of new business at annual/special meetings. As the Bylaws exist, new business can be introduced from the floor at the last business session, voted upon and enacted without review by any committee. This lack of review circumvents the usual system of checks and balances provided in the Bylaws. This issue was brought before the Executive Committee by Betty Dennis for discussion. The Executive Committee requested that this Committee send a survey to other state associations to gather information on how other groups handle new business and policy issues. The survey is in progress now and the results will be forwarded to the 1992-93 Committee for continuing consideration of this issue.

CHRISTIAN PHARMACISTS ELECT OFFICERS

A new slate of officers was elected at the recently concluded meeting of the Christian Pharmacists Fellowship International held at Campbell University at Buies Creek, North Carolina.

Elected were: Fred M. Eckel of Chapel Hill, President; R. David Anderson of Waynesboro, VA, Vice-President; Trent A. Tschirgi of Columbia, MD, Secretary; Jack Parrish of Chester, VA, Treasurer; and Warren E. Weaver of Richmond, VA, Executive Director.

Mr. Eckel had served previously as Vice-President of the Fellowship and as a board member. He received his BS in Pharmacy at the Philadelphia College of Pharmacy and Science in 1961 and an M.S. at Ohio State University in 1963. He is currently Professor and Chairman of the Division of Pharmacy Practice at the University of North Carolina. He has served on many boards and committees and is a past president of the American Society of Hospital Pharmacists. His memberships include the: American Association for the Advancement of Science, American Association of Colleges of Pharmacy, American College of Apothecaries, American Institute of the History of Pharmacy, American Pharmaceutical Association, American Society of Consultant Pharmacists, Canadian Society of Hospital Pharmacists, American Society of Hospital Pharmacists, North Carolina Pharmaceutical Association and the North Carolina Society of Hospital Pharmacists.

In addition, James Boyd of Buies Creek, NC, was elected to a three-year term of the Board of Directors. Dr. Boyd is a graduate of the University of Nebraska College of Pharmacy and has been Assistant Professor of Pharmacy Practice at Campbell University since 1990. He has held previous appointments at Creighton University and the University of Nebraska.

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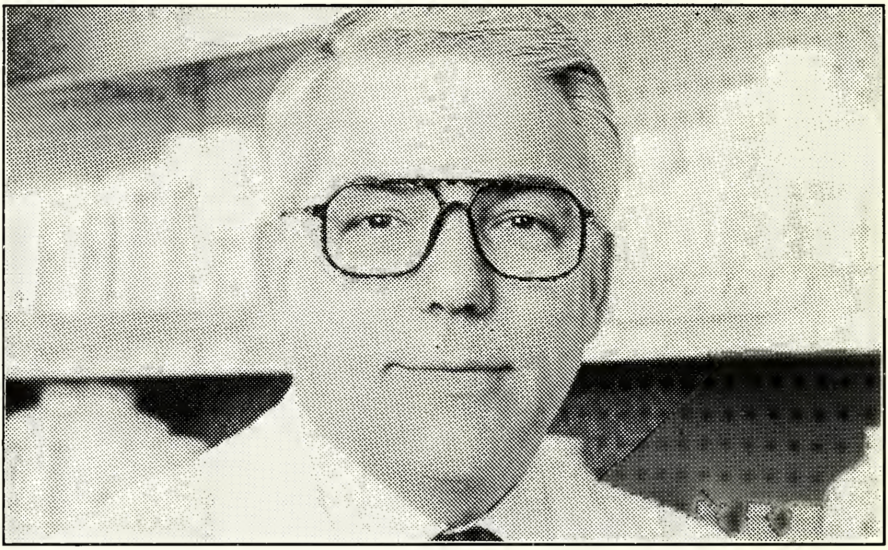

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CORRESPONDENCE COURSE

NEW DRUGS OF 1992
PART I: DRUGS FOR AIDS AND ANTI-INFECTIVE AGENTS

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to identify and discuss new drugs for AIDS and anti-infective agents.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. *exhibit knowledge of the pharmacologic classification and therapeutic considerations for each of the drugs discussed;*
2. *select from a list the indication, mechanisms of action, benefits and limitations of the drugs discussed;*
3. *identify adverse effects, major toxicities, and drug interactions associated with the drugs; and*
4. *demonstrate an ability to counsel patients on these new drugs.*

This article begins a discussion of new molecular-entity drugs approved by FDA or marketed since late 1991. It discusses drugs for AIDS and anti-infective agents *(Table 1)*. The remaining new drugs will be the focus of subsequent articles in this series.

New Drug Classification System

The FDA classification system used prior to 1992 *(Table 2)* categorized new drugs based upon their probable therapeutic worthiness for the particular indication(s) that the manufacturer requested when filing a New Drug Application (NDA). The designation as depicted in Table 2 for each drug, when known, is provided within the text.

Recently, FDA has initiated a refined system for classifying drugs according to their therapeutic potential. In effect now, all drugs that are submitted for an NDA will be assigned one of the following codes: *P* for *Priority* or *S* for *Standard.* Priority drugs are those with advanced therapeutic potential because there are no effective drugs available in this country for the indicated condition, the drug is more

Table 1
NEW ANTI-INFECTIVES AND DRUGS FOR AIDS

Generic Name	Trade Name	Classification	Dosage Form
Azithromycin	Zithromax (Pfizer)	Macrolide	Capsules: 250 mg
Cefprozil	Cefzil (Bristol-Myers Squibb)	Cephalosporin	Capsules: 250 & 500 mg Oral Suspension: 125 & 250 mg/5 mL
Clarithromycin	Biaxin (Abbott)	Macrolide	Tablets: 250 & 500 mg
Didanosine	Videx (Bristol-Myers Squibb)	HIV infection	Tablets: 25, 50, 100,& 150 mg Powder buffered: (single dose): 100, 167, 250 & 375 mg Powder pediatric: 2 & 4 gram
Foscarnet sodium	Foscarvir (Astra)	CMV retinitis*	Injection: 24 mg/mL
Lomeloxacin	Maxaquin (Searle)	Quinolone	Tablets: 400 mg
Loracarbef	Lorabid (Lilly)	Cephalosporin	Capsules: 200 mg Oral suspension: 100 & 200 mg/5 mL

*CMV (cytomegalovirus) retinitis is a common opportunistic infection of AIDS.

effective than currently available drugs, or it has other important advantages over alternate therapy such as improved pharmacokinetics or reduced toxicity. Drugs that are coded *S* will be those that are similar to others already available, corresponding to current *C* drugs.

Drugs for AIDS

Didanosine (1AA; Videx/Bristol-Myers Squibb). Also known as dideoxyinosine or ddI, didanosine is the second nucleoside analog to be approved for treatment of HIV infection. It is indicated for treatment of adults and children over 6 months of age who are intolerant or resistant to zidovudine (Retrovir), or who have experienced significant clinical or immunologic deterioration with zidovudine. In the early clinical trials, patients have displayed increased CD4 cell counts which suggests overall improvement in their disease. There are no definitive data regarding progression of HIV infection, or upon reducing the incidence of opportunistic infection. A study showed that combination therapy with zidovudine and didanosine works better than either drug alone to increase CD4 and T lymphocytes to higher levels in patients with advanced AIDS.

Didanosine is converted intracellularly to dideoxyadenosine triphosphate (ddATP), its active metabolite. Its mechanism of action, like that of zidovudine, is to inhibit reverse transcriptase, an enzyme required for replication of HIV.

Table 2

FDA'S 1991 SYSTEM FOR CLASSIFYING NEW DRUGS

Chemical/Pharmaceutical Standing

1=Chemical entity
2=New salt form
3=New dosage form
4=New combination
5=Generic drug
6=New indication
7=Drug already marketed but without approved NDA Therapeutic Potential

A=Important (significant) therapeutic gain over other drugs currently marketed in the U.S.
AA=Important therapeutic gain, indicated for AIDS patients: fast-track treatment
B=Modest therapeutic gain
C=Important options; little or no therapeutic gain

Serious toxicities differ from those of zidovudine. Of particular importance is the low incidence of serious hematologic disturbance, including granulocytopenia or anemia, which are major toxicities with zidovudine.

The toxicity of greatest concern for didanosine is pancreatitis which developed in 9 percent of patients in early clinical trials who were taking the drug at or below recommended dosages. For this reason, any person who develops severe nausea and vomiting, abdominal cramps, or elevated amylase levels, should be evaluated for pancreatitis, and therapy with didanosine be suspended until a definitive diagnosis is made. If possible, didanosine should not be used in persons with a history or pancreatitis or alcoholism, or concurrently with other drugs with pancreatic toxicity.

Peripheral neuropathy characterized by burning, tingling, pain or numbness in the hands or feet, is another important adverse reaction to didanosine. It occurs in 34 percent of patients in early clinical trials who were treated with doses at or below the recommended levels.

Headache and diarrhea were also reported, each appearing in about one-third of patients. In clinical trials, the individual packet dosage forms were associated with the highest incidence of diarrhea. If this is a problem, one of the other formulations might be tried. Other reactions included nausea and vomiting, abdominal pain, rash and pruritus, and insomnia, each occurring in 20 to 25 percent of patients; and constipation, depression, pain, taste disturbance, inflammation of the mucous membranes in the mouth, muscle pain, arthritis and elevated hepatic enzymes, each occurring in 10 to 20 percent of patients.

Videx is commercially available in three formulation types. Since didanosine is destroyed in acidic solution, such as the gastric fluids, it must be buffered to protect it from degradation. Two of the formulations, the chewable/dispersible tablets and the single-dose packets, are pre-buffered. The 2 and 4-gram powders for oral solution products must be mixed with an antacid prior to administration. Since each formulation has unique reconstitution and administration techniques, a short description of them is in order.

Videx tablets are buffered with dihydroaluminum sodium carbonate and magnesium hydroxide, and flavored with aspartame and sucrose. They are best protected from gastric acid when ingested as a solution. Therefore, the tablets should be chewed thoroughly and swallowed with some water. Alternatively, the tablets can be added to a least one ounce of water and mixed thoroughly until dispersed. The resulting liquid should be consumed immediately.

To assure adequate buffering, at least two tablets should be given at one time. For example, Videx is available in 25, 50, 100 and 150 mg tablet strengths; but a 150 mg dose should be given with a 100 mg tablet plus a 50 mg tablet.

The single dose powders are to be mixed with approximately four ounces of water (no fruit juices or other acidic liquids), stirred several minutes until completely dissolved, and then swallowed immediately. These formulations are buffered with dibasic sodium phosphate, sodium citrate and citric acid, and flavored with sucrose. They are available in 100, 167, 200 and 375 mg packets, and can be given as such in the proper dosage. The two-tablet dosage described above is not indicated for the oral solution packets.

The third formulation, Powder for Oral Solution–Pediatric, must be reconstituted to an initial solution of 20 mg/mL of *Purified Water* USP (i.e., no preservatives or buffers) to the 2-gram and 4-gram bottles, respectively. Then, they must be diluted to a final concentration of 10 mg/mL with an equal amount of a high potency liquid antacid such as Mylanta Double Strength or Maalox TC.

The resulting suspension is stable for three days in the refrigerator. Patients and caregivers should be advised to shake the container well before administering each dose. Since food reduces the bio-availability of didanosine by as much as 50 percent, all doses should be taken at least one hour before or two hours after meals.

Other factors to consider include the sodium content of some of the dosage forms. Videx tablets contain 264.5 mg of sodium; the packets of buffered powder have 1,380 mg of sodium. This must be taken into account in patients on a sodium-restricted diet, which is rare but possible in AIDS patients.

The tablets also contain magnesium and aluminum salts as does the oral solution after mixing half-and-half with an antacid. If patients taking these dosage forms are also receiving a tetracycline, quinidine, digoxin or other drugs that interact with antacids, at least one hour (preferably two) should elapse between doses of didanosine and the interacting drug. The packets should be dosed similarly.

Another important point is that the tablet dosage form of didanosine provides 20 to 25 percent greater than the solution prepared from the buffered powder. This accounts for the difference in adult dosage between the two forms, i.e., 200 mg every 12 hours with the tablets, and 250 mg every 12 hours with the buffered powder dosage form.

Didanosine is eliminated to great extent through the kidney. Patients with renal impairment should receive reduced doses.

Moreover, because of the high magnesium content of each tablet (15.7 mEq), patients with renal impairment may experience significant magnesium overload, especially after chronic dosing.

A third nucleoside analog, zalcitabine (ddC), has been recommended for approval for use in combination with zidovudine for the management of HIV-infected adult patients with AIDS or advanced HIV disease (CD4 cell count less than 300/mL). Peripheral nerve damage is the adverse effect of greatest concern. When released, ddC will be marketed as Hivid, by Roche Laboratories (Editor's note: *Hivid received final approval for marketing in June 1992.*)

Foscarnet Sodium (1B; Foscarvir/ Astra). Foscarnet is indicated for treatment of cytomegalovirus (CMV) retinitis in patients with AIDS. This opportunistic infection occurs in up to 30 percent of patients with AIDS, and is a leading cause of blindness.

The drug inhibits DNA synthesis by inhibiting viral DNA polymerase. Foscarnet differs from the other commercially available drug for CMV retinitis, ganciclovir (Cytovene), in that it is active itself. Therefore, it does not require phosphorylation to an active triphosphate form. It is not a cure for CMV retinitis, but delays progression of the disease.

Granulocytopenia has been reported in some patients taking foscarnet, although the problem is less significant than with ganciclovir. Consequently, foscarnet is especially useful in patients who are also receiving zidovudine.

A major concern with foscarnet is development of renal impairment which occurs in most patients who receive it. It becomes most significant during the second week of therapy, but can appear anytime. Creatinine clearance should be determined at initiation of therapy, two to three times during induction of therapy, and every 1 to 2 weeks during maintenance therapy. Adequate hydration of the patient must be maintained, and foscarnet should not be administered concurrently with other nephro-toxic drugs.

Foscarnet can chelate with divalent metal ions and other electrolytes; hypocalcemia, hypomagnesemia, hypokalemia and hypophosphatemia are all reported. Serum electrolytes should be monitored for creatinine clearance.

The drug may also be useful in treating other CMC infections. However, it is not officially indicated for these infections at this time.

Foscarvir is supplied as a 24 mg/mL solution in 250 and 500 mL bottles for administration by intravenous infusion only.

Anti-infectives

Cephalosporins

Two cephalosporin antibiotics were approved for marketing at the end of 1991: cefprozil and loracarbef. At the time of writing this article, the total number of cephalosporins approved in the U.S. was 22 (several have been approved but are not marketed at this time). This makes the cephalosporins the most widely prescribed of all antibiotic groups. A major reason for this popularity is their broad spectrum of activity and low order of side effects.

It is of interest that both cefprozil and loracarbef were approved by FDA shortly before the patents expired on major market-share cephalosporins currently distributed by their manufacturers. These are Duracef (Bristol-Myers Squibb) and Ceclor (Lilly/Dista). This latter product is the world's leading selling cephalosporin and represents a significant percentage of Lilly's overall sales This makes these drug approvals very opportune for their respective manufacturers.

Cefprozil and loracarbef act in the same manner as other cephalosporins and penicillin derivatives. They inhibit peptide incorporation into the developing new cell wall as susceptible organisms reproduce. This damages their ability to maintain an osmotic gradient. Water rushes into the bacteria through the defective cell wall and causes it to swell and burst. Therefore, these antibiotics are bactericidal.

Cefprozil (1C; Cefzil/Bristol-Myers Squibb). This cephalosporin is indicated for treatment of mild to moderate infections of the skin, middle ear, and respiratory tract.

As with other cephalosporins, adverse effects are relatively rare. Those seen involve the GI tract, with nausea, vomiting, diarrhea, and abdominal pain reported most often. In clinical trials prior to marketing, only 2 percent of patients discontinued the drug due to adverse effects. The manufacturer reportedly will be trying to cut into both the Suprax and Ceclor markets.

Cefprozil is supplied is 250 mg and 500 mg capsules, and as 125 mg/5mL and 250 mg/5 mL powder for oral suspension. It is administered 1 to 2 times daily.

Loracarbef (1C; Lorabid/Lilly). This is an oral, semi-synthetic carbocephem antibiotic similar structurally and therapeutically to cefaclor (Ceclor). It is indicated to treat infections of the upper and lower respiratory tract, skin and skin structure, and urinary tract.

Adverse reactions reported in clinical trials were similar to those of other betalactam antibiotics. Gastrointestinal effects, headache, and skin reactions were most common.

Although approved for marketing in late 1991, Lorabid is not expected to be available until later in 1992. This strategy to delay marketing is reportedly due to the manufacturer's desire to make a major impact by releasing it at the onset of the Fall cold and flu season. Another theory states that Lilly will try to successfully protect its manufacturing process for Ceclor as Bristol-Myers Squibb did with Duracef, thereby extending its exclusive distribution for several years.

Lorabid will be available as 200 mg capsules, and 100 mg/5 mL and 200 mg/5 mL powders for oral suspension. Twice-daily dosing on an empty stomach is recommended, although it can be taken with meals.

Macrolide Antibiotics

Azithromycin and clarithromycin are macrolide antibiotics, as are erythromycin in that they have greater stability in gastric juices and a longer duration of action.

Both azithromycin and clarithromycin are well tolerated. Neither is associated with the relatively high incidence of upset stomach and nausea that is characteristic of erythromycin. The claim is made that their spectra of activity include organisms susceptible to both erythromycin and the cephalosporins.

These agents, as do the erythromycins, act on susceptible bacteria by interfering with protein synthesis and preventing replication. The body's defense mechanism then eradicates the infective organisms. Therefore, they are bacterio-static.

Azithromycin (1B; Zithromax/Pfizer). Azithromycin is two to four times less active than erythromycin against streptococci and staphylococci. Like clarithromycin, erythromycin-resistant streptococci and staphylococci are also resistant to azithromycin. When released to the market place, Zithromax was approved for use in treating upper and lower respiratory tract infections, skin and soft tissue infections, and non-gonococcal urethritis and cervicitis caused by chlamydia.

For most of its indications, azithromycin is dosed 500 mg to start, then 250 mg once daily for 4 more days for a total dose of 1.5 grams. For non-gonococcal urethritis and cervicitis caused by chlamydia.

For most of its indications, azithromycin is dosed 500 mg to start, then 250 mg once daily for 4 more days for a total dose of 1.5 grams. For non-gonococcal urethritis and cervicitis, it is given as a single 1 gram dose. Even though it is relatively acid-stable, azithromycin must be taken at least one hour before, or two hours after a meal to maximize its absorption. The product is available as 250 mg capsules.

Clarithromycin (1B; Biaxin/Abbott). Clarithromycin has about two to four times more activity than erythromycin against respiratory and skin/soft tissue infections caused by streptococci and staphylococci, unless they are resistant to erythromycin. Like erythromycin, clarithromycin is indicated for treating respiratory and middle ear infections, caused by the *Haemophilus influenzae, Moraxella catarrhalis, Legionella pneumophila, Mycoplasma pneumoniae,* and *S. pneumoniae.*

Food delays absorption of clarithromycin slightly and the formation of its active metabolite. However, the overall bioavailability is not affected, and clarithromycin may be given without regard to food. Clarithromycin has been reported to elevate theophylline administration, the manufacturer recommends that patients taking both drugs should be monitored carefully.

The usual dose is 250 to 500 mg every 12 hours. Biaxin tablets are supplied in 250 and 500 mg strengths.

Quinolones

Three new quinolone (fluoroquinolone) derivatives have been approved. The manufacturer of one (enoxacin/Penetrex—Parke-Davis) has reportedly not yet decided whether to proceed with marketing; at the time of writing this article, the drug is not available. The manufacturer of another, temafloxacin (Omniflox/Abbott) voluntarily withdrew its drug in June 1992, while studies were undertaken to determine why there was a higher incidence of seizures than that seen in clinical trials. The new quinolone, **lomefloxacin (1C; Maxaquin/Searle)**, joins ciprofloxacin (Cipro), norfloxacin (Noroxin) and ofloxacin (Floxin).

Their mechanism of action is unique among antibiotics. The quinolones inhibit bacterial DNA gyrase, the enzyme that controls uncoiling and recoiling of bacterial chromosomal DNA. This prevents separation of interlocking DNA strands, and hence, interferes with bacterial replication. The quinolones are both bacteriostatic and bactericidal; therefore, they are active against bacteria in both resting and reproductive phases. Because quinolone antibiotics do not bind significantly with human enzymes, they are relatively safe.

Quinolones display a broad spectrum of action against numerous Gram-positive and Gram-negative organisms including *Pseudomonas aeruginosa.* They are agents of choice for *Campylobacter jejuni,* an organism that causes intestinal infections, and may be associated with peptic ulcer disease. They are active against enterococci, staphylococci (including methicillin-resistant strains), *N. gonorrhoeae,* and are back-up therapy for enterobacter, escherichia, klebsiella, proteus, providencia, and vibrio infections.

All quinolones are well tolerated. Gastric symptoms that have been reported include nausea, vomiting, and diarrhea. Agitation, dizziness, headache, insomnia, and seizures have been rarely reported. Photosensitivity and crystaluria have been rarely noted for the quinolones as a group. Most of these adverse effects were seen with earlier available quinolones, and although uncommon, are included in the adverse effects section of the product labeling of all quinlones.

Unlike other quinolones whose administration is recommended on an empty stomach, lomefloxacin may be taken without regard to meals or food. Moreover, the new quinolone reportedly does not interfere with the metabolism of theophylline, and may be a safer alternative to other quinolones in persons needing both classes of drugs. Lomefloxacin has the advantage over all other quinolones in that its biological half-life of 8 hours permits once-daily dosing.

A professional development program made possible by an educational grant from

SEARLE

Orally-administered quinolones offer significant cost savings over injectable antibiotics. In the hospital, their use eliminates the need for reconstitution of dry powders, admixture supplies, diluents and IV fluids, administration sets, and the personnel time required to administer and monitor intravenous therapy. In the community, they provide broad-coverage against many common bacteria, and can be administered to outpatients.

Maxaquin is supplied in 400 mg film-coated tablets. Its recommended dose is 400 mg once a day for 10 days in bronchitis and cystitis, and for 14 days in uncomplicated urinary tract infections.

Patient Advice for the New Antibiotics

Cefzil. Each dose should be taken with a full glass of water. Absorption is best on an empty stomach, but if it causes gastric upset, it can be taken with food. Following reconstitution, the liquid forms should be stored in the refrigerator, used within 14 days, and be shaken well before each administration. An accurate measuring device should be offered to the patient.

Patients should be advised to take all of the prescribed medication, even if they feel better, to help eradicate the infective organisms. Some patients may experience diarrhea while taking Cefzil. Mild diarrhea usually stops after a few days of therapy. Severe diarrhea should not be self-treated since it may be caused by an overgrowth of a nonsusceptible colony of microorganisms requiring physician-intervention. OTC adsorbent antidiarrheals may interfere with the action of the antibiotic and antiperistaltics may worsen the problem.

If the patient misses a dose, he should take it as soon as he remembers. If it is time for the next dose, the patient should double that dose, then go back to the regular dosing schedule.

The following adverse effects should be reported to the physician: skin rash, hives or itching, facial swelling, shortness of breath or wheezing, prolonged nausea or vomiting, and persistent sore throat or high fever.

Biaxin and Zithromax. Each dose should be taken with a full glass of water. Biaxin can be taken with food or on an empty stomach, but Zithromax should be taken at least one hour before or two hours after a meal to maximize absorption.

Patients should be advised to take all of the medication, even if they feel better, to help eradicate the infective organisms. Some patients may experience diarrhea while taking Biaxin or Zithromax. Mild diarrhea usually disappears after a few days of therapy. Severe diarrhea should not be self-treated since it may be caused by overgrowth of a nonsusceptible colony of microorganisms requiring physician intervention. OTC adsorbent antidiarrheals may interfere with the action of the antibiotic and antiperistaltics may worsen the problem.

If the patient misses a dose, he should take it as soon as he remembers. If it is almost time for the next dose, he should space the missed dose and the next dose 5 to 6 hours apart. Then, he should go back to his regular schedule. The following adverse effects should be reported to the physician: prolonged or severe nausea, vomiting or diarrhea.

Maxaquin. Maxaquin can be taken with food or on an empty stomach. If stomach upset occurs, it can be taken with food. Antacids and iron supplements can interfere with the absorption of Maxaquin. They should not be taken within two hours of this medication. Patients should drink lots of fluids (at least 6 to 8 glassfuls per day) while taking this medication.

Some individuals experience dizziness, blurred vision or drowsiness from this medication. Patients should be careful driving or performing hazardous tasks until they determine how they react to it, and exercise caution if these effects occur.

This medication may make some patients' skin more sensitive to sunlight or sunlamps. They should avoid excessive exposure to ultraviolet light, and use a sunblock product of at least SPF 15 to minimize problems. If the patient misses a dose of Maxaquin, he should take it as soon as possible. If it is almost time for the next dose, he should take the missed dose, the next dose 10 to 12 hours later, and then resume the once-daily regimen.

The following adverse effects should be reported to the physician: skin rash, nausea, vomiting or diarrhea, headache, blurred vision, excessive dizziness or drowsiness, stomach pain or dry mouth.

CORRESPONDENCE COURSE QUIZ

New Drugs 1992, Part 1: AIDS and Anti-infective Agents

1. The mechanism of action and chemistry of Biaxin is most closely similar to which of the following?
   a. Quinolones
   b. Cephalosporins
   c. Tetracycline
   d. Erythromycin

2. Didanosine exerts its mechanism of action by inhibiting the enzyme:
   a. alkaline phosphatase.
   b. DNA polymerase.
   c. reverse transcriptase.
   d. viral nucleotase.

3. "Take each dose at least one hour before or two hours after meals" is MOST appropriate for:
   a. Biaxin.
   b. Cefzil.
   c. Maxaquin.
   d. Zithromax.

4. The toxicity of greatest concern with Videx is:
   a. pancreatitis.
   b. anemia.
   c. renal impairment.
   d. agranulocytosis.

5. Which of the following acts by inhibiting the enzyme DNA gyrase?
   a. Biaxin
   b. Cefzil
   c. Maxaquin
   d. Zithromax

6. Videx tablets are best administered as a 2-tablet regimen to assure:
   a. adequate buffering.
   b. water solubility.
   c. better taste.
   d. sufficient surface area.

7. Foscarnet exerts its mechanism of action by inhibiting the enzyme:
   a. alkaline phosphatase.
   b. DNA polymerase.
   c. reverse transcriptase.
   d. viral nucleotase.

8. Patients receiving which of the following should be advised to avoid excessive exposure to sunlight and ultraviolet light?
   a. Biaxin
   b. Cefzil
   c. Maxaquin
   d. Zithromax

9. The toxicity of greatest concern with foscarnet is:
   a. pancreatitis.
   b. anemia.
   c. renal impairment.
   d. agranulocytosis.

10. Which of the following acts by inhibiting peptide incorporation into developing new cell walls as susceptible organisms are reproducing?
   a. Biaxin
   b. Cefzil
   c. Maxaquin
   d. Zithromax

Cut out or Reproduce and Mail

CONTINUING PHARMACEUTICAL EDUCATION (CPE)

New Drugs 1992, Part 1: AIDS and Anti-infective Agents

- Attach a mailing label from *The Carolina Journal of Pharmacy* or print your name and address and mail to CE Test, NCPhA, P.O. Box 151, Chapel Hill, NC 27514–0151
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- **This is a member service. Non-member tests will not be graded nor CPE credit hours given.**
- NCPhA will maintain a copy of your completed CPE tests and upon successful completion of each program, will issue a certificate for one (1) hour of North Carolina Board of Pharmacy approved CPE credit.
- If more than two (2) questions are answered incorrectly, the test is failed. You will be given one (1) opportunity to submit a second answer sheet.

Please circle correct answer

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3. a b c d
4. a b c d
5. a b c d
6. a b c d
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9. a b c d
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CLINICAL COORDINATOR: Cape Fear Valley Medical Center is seeking a clinical coordinator to plan, organize and supervise the clinical activities of the department. Specific responsibilities include training and supervision of staff pharmacists in clinical activities, maintaining and updating the departmental QA program, drug utilization reviews, and monitoring of drug therapy. Candidates should possess a Pharm.D. and be eligible for licensure in NC. Postgraduate experience is desirable. Cape Fear Valley Medical Center is a 506-bed regional referral hospital located in eastern NC. Residents enjoy seasonal weather changes with easy access to the mountains or seashore. Major universities are within commuting distance. The hospital offers virtually every specialty and sub-specialty in treatment. Competitive salary and benefits are offered. Travel and lodging will be arranged for interviewing. If you are looking for a progressive facility in which to expand your professional experience, contact: Lib Whittington, Personnel Department, (919) 323-6646 or P.O. Box 2000, Fayetteville, NC 28302.

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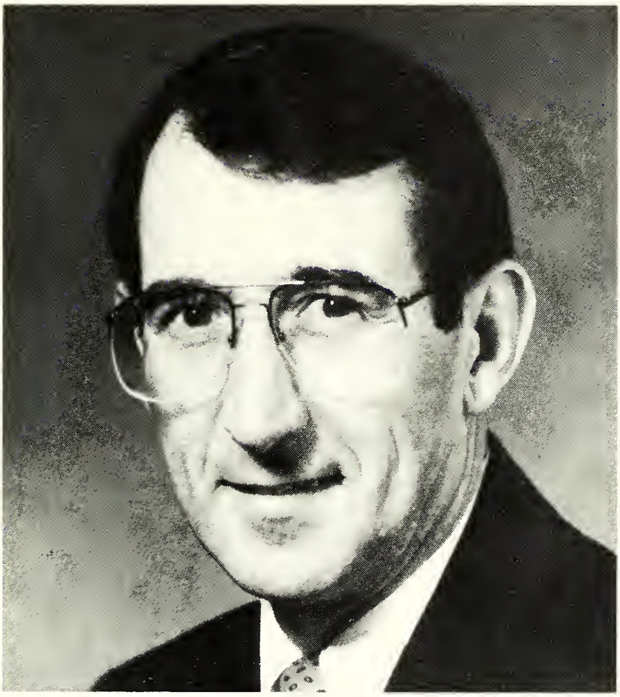

UNC School of Pharmacy Dean William H. Campbell.

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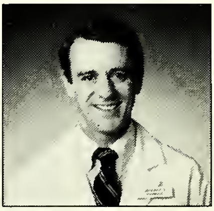
Important figures in diabetes care

7

Diabetes is the **No. 7** cause of death in the US[1]

1

Diabetes is the **No. 1** cause of new blindness in persons aged 20-74[1]



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1. *Diabetes Surveillance, 1980-1987.* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

GETTING TO KNOW THE DEAN

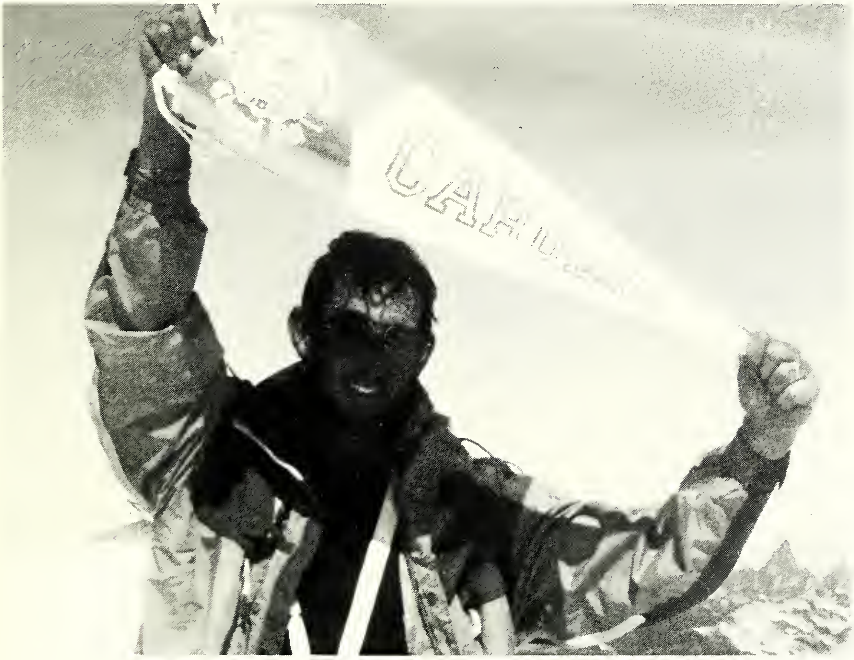
by Kristin McKeithan
UNC School of Pharmacy

"The legacy of the UNC School of Pharmacy is one of leadership in the profession of pharmacy. Because you have joined this legacy, you do not have the choice of whether or not to be a leader. You are a student at UNC, therefore you are a leader." These are some of the first words the Class of 1995 heard in Beard Hall at their orientation on August 24, 1992. Dean William Campbell was busy urging students to excel in the classroom and diligently promote the profession of pharmacy. He also attended the annual Academy of Students of Pharmacy Back to School Picnic, where he took the opportunity to meet and socialize with dozens of students. (He also slaved over the grill cooking hamburgers and hotdogs.) In between all of the hustle and bustle, Dean Campbell took time to share with me his ideas for UNC, his vision for pharmacy, and his personal goals.

Journal: *What attracted you to the UNC School of Pharmacy?*

Dean Campbell: "The timing was right. At Auburn I felt I had accomplished most of the goals I had set. And even more importantly, I have always carried a tremendous respect for Tom Miya and the faculty at UNC, as well as an enormous regard for the University as an institute of higher education. As I met with members of the faculty and heard their comments about their desire to achieve excellence, willingness to embrace change, and concern about professional curricula and students, I felt UNC and I could be a good fit."

What do you see as UNC's greatest strength?
"I haven't had enough time to meet with all of the students as of now—this is only my fifth day. But, judging by their excellent paper credentials, I would venture to say that the student body is one of the school's greatest



Dean Campbell carries UNC School of Pharmacy to new heights.

strengths. Obviously, the faculty is of high quality and represents a breadth of areas. In this faculty there are areas of expertise ranging from molecular biology to pharmaco-economics. The alumni also appear to be a tremendous asset over their long years of support and involvement with the school. The development of the Foundation to provide financial help and the various advisory groups that are always willing to provide services and support are critical elements to this school's success."

What are some areas for improvement? "A high priority is to correct the deficiencies of the building in terms of safety and utilities, as well as improve the efficiency of the use of space. There is a need to revisit the curriculum and develop and expand on new areas of course work and ways to teach the curriculum."

One of my vices is to climb mountains. My personal goal is to climb every volcanic peak in the U.S. I'm very active in the outdoors and now that I'm in North Carolina, I'm going to try my hand at golf.

What do you see as the greatest changes facing pharmacy in the next two decades, and how will these affect the training of pharmacy students? "I see three changes presently occurring in pharmacy that must be addressed in the schools. The first is a concentration on the pharmacist as a communicator to patients and health professionals. The pharmacist's time dispensing and distributing medication is steadily decreasing, with an increase in counseling patients and advising other health care professionals. The pharmacist of the future will be a patient educator and a drug therapy monitor. Secondly, we must focus on the effective management of resources. The pharmacist must manage technicians, computers, formularies, and plasma concentrations among other things. These resources must be managed efficiently to maintain a high standard of practice. Finally, specialization is evolving within the practice of pharmacy and we must be ready for it. These three areas will have to be represented in the curriculum."

What must be done before UNC offers a single entry-level Pharm.D. degree? "I would like to see us do what is right for North Carolina and not be heavily influenced by national trends. We must make sure the new Pharm. D. degree is truly a different and improved degree. There are three vital areas to investigate before moving forward. They are the impact on manpower, the opportunity for all graduates to practice at their level of training, and the availability of faculty, staff, and clinical sites. All of pharmacy is in a transition period. It is up to a few schools like UNC to lead the way through this time and show other schools the correct way to make a change."

What is your management style? "My style can be called participative and decentralized management. In order to have an excellent program, both the faculty and I must work together to implement ideas and be accountable for our decisions."

What do you see as the role of student pharmacy organizations, and how will you promote student involvement? "Student organizations are central to a student's experience. I have told students that they are leaders. Being a leader means starting as a student and being involved in organizations. It is imperative for students to join organizations. My role will be to assist students in attending regional and national meetings and encourage participation now in organizations throughout their careers. I am here to do whatever I can."

Do you have any ideas of areas that faculty and graduate researchers may wish to pursue? "The research choices that have been made to date are completely appropriate, with major concentrations in medicinal chemistry, pharmaceutics, pharmacy administration, and pharmacotherapeutics/drug development. Within these areas the choice of concentration, for example pharmacogenetics as a topic within pharmaceutics, is best left to the respective divisions. I would, however, like to see research expanded in practitioner scholarship or practice-based research. I want the UNC School of Pharmacy to achieve a tradition of scholarship generated by practicing pharmacists identifying critical issues and helping the school faculty address the research."

What activities do you engage in outside of pharmacy? "One of my vices is to climb mountains. Annually, I conduct an expedition with several other people and we climb a major peak in the United States. My personal goal is to climb every volcanic peak in the US. I'm very active in the outdoors—hiking and running. And now that I'm in North Carolina, I'm going to try my hand at golf."

What do you want to do when you grow up? "Karen, my wife who is also a pharmacist, and I have decided that at the end of our careers, we would like to join the Peace Corp and work as pharmacists in underdeveloped countries, possibly in South America. Another option is to join the Indian Health Service serving the Native American population. We would like to finish our careers helping individuals on a daily basis in ways that will make a real difference in their lives."

I came away from this interview much impressed with Dean Campbell's vision of the future for the UNC School of Pharmacy. His oal is to make one of the best pharmacy schools in the nation even better. In doing so, the school will continue to produce top-notch professionals who will be leaders in pharmacy well into the future. He believes that the legacy of the UNC School of Pharmacy is one of leadership. Having Bill Campbell as Dean greatly expands this legacy.

William H. Campbell, Ph.D., Dean

Dean Bill Campbell is a native of Culver, Oregon and earned his bachelor of science in pharmacy and a master of science in pharmacy administration from Oregon State University. His doctoral degree in pharmacy administration was earned at Purdue University.

Campbell served on the faculty of the Oregon State University School of Pharmacy as Assistant Professor in the Department of Pharmacy Administration. He was on the faculty of the University of Washington School of Pharmacy for 13 years and chaired the Department of Pharmacy Administration. While at the University of Washington, he was also professor in the Department of Health Services, School of Public Health and Community Medicine. He joined the Auburn University School of Pharmacy in 1988 as dean. He also served as professor in the Department of Pharmacy Care Systems and as adjunct professor at the University of Alabama at Birmingham School of Public Health. In between faculty appointments, Campbell was a senior researcher at the National Center for Health Services Research in Hyattsville, MD.

Campbell has been active in pharmacy organizations, academic, scientific, as well as professional. He was president of the American Association of Colleges of Pharmacy. He received the Distinguished Alumnus Award from the Purdue University College of Pharmacy and Pharmacal Sciences. He has been a consultant to the APhA Commission on Third Party Programs, a member of the Board of Directors of the American Foundation for Pharmaceutical Education, a member of the Commission on Goals of the American Society of Hospital Pharmacists, a member of the Pharmacy Committee. Medical Care Section of the American Public Health Association, as well as numerous Committees of state and local pharmaceutical associations. He serves as consultant for many organizations. When he left Auburn to come to UNC, he listed membership in national pharmacy and health-related organizations as well as the Alabama Pharmacists Association, the Alabama Society of Hospital Pharmacists and the Georgia Society of Hospital Pharmacists. He is licensed to practice pharmacy in Alabama, Oregon and California.

Dean Campbell is a much-sought-after speaker and is author of many articles which have appeared in such publications as the *American Journal of Pharmaceutical Education*, the *American Journal of Hospital Pharmacy, Computers in Pharmacy, Drug Intelligence and Clinical Pharmacy, Medical Care* and *Medical Marketing and Media.*

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I certify the statements made by me above are correct and complete.

Alfred H. Mebane III,
Editor
September 25, 1992

PHARMACY LAW CAPSULE

by James Boyd, Pharm.D., M.B.A.
Assistant Professor
Department of Pharmacy Practice
Campbell University School of Pharmacy

ANABOLIC STEROIDS

In the past few years it has become apparent, primarily through the news media, that an increasing number of athletes and trainers have misused and encouraged the misuse of anabolic steroids. Since the 1950s the experimentation by athletes with anabolic steroids has escalated. Anabolic steroids, through a hormonal manipulation mechanism, increase muscle mass, strength and weight. The long term adverse effects, which many times are unknown to the athletes, include: coronary heart disease, prostatic hypertrophy, bleeding ulcers, liver abnormalities, testicular atrophy, impotence, gynecomastia and other complications. The use of these agents should be discouraged for this purpose. *(Micromedex Inc., Vol 70, 1991)*

Because of the potential for harmful side effects, legislation has been enacted addressing this issue. The Omnibus Crime Control Bill (P.L. No. 101-647) passed and signed by President Bush on November 29, 1990, included the Anabolic Steroids Control Act of 1990. As defined in the Act, "the term anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestin, and corticosteroids) that promotes muscle growth, includes:

(1) boldenone
(2) chlorotestoterone (4-clortestosterone)
(3) clostebol
(4) dehydrochlormehtyltestosterone
(5) dihydrotestosterone (4-dihydrotestosterone)
(6) drostanolone
(7) ethylestrenol
(8) fluoxymesterone
(9) formebulone (formebolone)
(10) mesterolone
(11) methandienone

James A. Boyd

(12) methandranone
(13) methandriol
(14) methandrostenolone
(15) methenolone
(16) methyltestosterone
(17) mibolerone
(18) nandrolone
(19) norethandrolone
(20) oxandrolone
(21) oxymesterone
(22) oxymetholone
(23) stanolone
(24) stanozolol
(25) testolactone
(26) testosterone
(27) trenbolone
(28) any salt, ester or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth."

The Act designated anabolic steroids as Schedule III Controlled Substances. The classification in Schedule III moves the enforcement to the Drug Enforcement Administration (DEA) and pharmacies dispensing these products must have a current DEA registration. (See *North Carolina Board of Pharmacy Newsletter*, April, 1991 for specific procedures if your pharmacy does not have a DEA registration.) As of February 27, 1991, all pharmacy registrants handling anabolic steroids were required to comply with all the requirements of the Federal Controlled Substance Act. This includes recordkeeping, dispensing, destroying, and inventorying.

As a matter of procedure, if your pharmacy stocked anabolic steroids on or after February 27, 1991, appropriate inventory records are required. An initial inventory of the stock should have been taken February 27, 1991. The Federal Controlled Substances Act requires a pharmacy registrant to take a complete inventory of all controlled substances on hand every two years after the initial inventory was taken. Since many pharmacies inventory on May 1 in odd-numbered years, an inventory of the anabolic steroids should be included with the May 1, 1991 inventory for those who inventory on that date.

As a suggestion, if you failed to include the anabolic steroid inventory on the appropriate dates, correct the omission and take an inventory immediately. An omission of negligence will most likely be viewed more favorably if the omission is handled honestly, and corrected to your best ability.

References available upon request.

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THE CLINICAL AND LEGAL IMPLICATIONS OF SWITCHING INSULINS

by Lenore T. Coleman, Pharm.D., and Richard R. Abood, J.D.

Reprinted with the permission of the California Pharmacist Feb. 1992

CLINICAL ISSUES

Insulin was first isolated and commercially produced in the 1920s.[1] During the last seventy years, commercially available insulins have undergone many developmental changes. These include the crystallization of the insulin molecule, the development of modified insulins, the introduction of protein purification procedures, and the production of human insulin through enzymatic conversion and recombinant DNA technology. All the changes have strived to produce a commercially available pure insulin with the same structure as endogenous human insulin. Currently insulin is derived from two sources.

Animal Species Insulins

- pure pork (porcine)
- pure beef (bovine)
- beef-pork mixture (70% bovine and 30% porcine)

Human Insulins

- recombinant-DNA technology (rDNA). Biosynthesis of human insulin using either clones of Escherichia coli (bacteria), introduced by Lilly in 1983, or Saccharomyces cerevisiae (yeast).
- semi-synthetic. Enzymatic conversion of pork insulin to human insulin by transpeptidation, in which there is replacement of B-30 alanine in pork insulin with threonine. Semi-synthetic insulin is manufactured by NovoNordisk but is being phased out by their rDNA yeast product.

There are many factors which affect the time-activity characteristics of the insulin preparations. Some of these factors are outlined in Table 1. Differences can occur between formulations of insulins from one manufacturer to another. These differences include the source of insulin, purity or composition of the individual formulation. There may be increases or decreases in the incidence of local or systemic allergy, serum insulin concentration, serum antibody concentration and insulin requirement.[2] The study by Galloway et al. showed that it is impossible to predict which patients will experience a dose change and in which direction the change will occur.[3]

The clinical implication of switching insulin is based on the kinetics, immunologic and side effect profiles of the different insulins.

Immunogenicity

Human insulin is substantially less antigenic (i.e., lowering of anti-insulin antibody titer) than bovine-porcine insulin but only slightly less antigenic than purified procine preparations. Human insulin has a reduced immunogenicity (i.e., fewer patients have the induction of insulin antibodies). The importance of circulating antibodies on diabetic control is controversial. In general, the lower the titer of insulin antibodies the better the postprandial glucose control. The long-term metabolic control does not seem to be influenced by the antigenicity of the insulin preparation.[4]

Kinetics

Human insulins have an earlier onset and peak and shorter duration of action than animal species insulins.[5] This is probably due to human insulins being more rapidly absorbed after subcutaneous administration. The more rapid absorption of human insulin provides for better postprandial glucose control.[4]

Side Effect Profile

The occurrence of lipodystrophies has decreased with the use of "purified monocomponent insulins." Lipoatrophy is still reported with the use of both human and procine insulins. It appears the atrophy may be due to a local immune response. Zinc and protamine in the modified insulins have been implicated in enhancing the immunological reaction and thereby causing the atrophic process.[6] Lipohypertrophy occurs due to the local anabolic effects of insulin promoting fat and protein synthesis. This effect may occur with any insulin preparation.

Insulin allergy appears to be caused by insulin antibodies. Virtually all insulin-treated diabetics develop antibodies. Causative agents include the insulin molecule, insulin dimers, pro-insulin-like substances or additives in insulin preparations.[7] Studies have shown that patients can be allergic to both animal and human insulins.[8,9] Insulin allergy is a risk when switching species type or brand of insulin and can only be anticipated by skin tests or a patient's initial response after multiple doses of the new insulin.

TABLE 1

Factors affecting the time-activity characteristics of insulin preparations.

- **dose of insulin used**
- **site of injection**
- **depth of injection**
- **exercise of the injection area**
- **massage of the injection site**
- **insulin antibody concentration**
- **insulin receptor dynamics**

Hypoglycemia is a common and potentially serious complication of insulin therapy. In the Diabetes Control and Complication Trial 9.8% of subjects in the standard treatment group had severe hypoglycemia during the 12 months of study.[10] Studies have shown between 2% and 7% of deaths in insulin-dependent diabetics were caused by hypoglycemia.[11] There have been reports which describe an increased frequency of hypogly-cemia with human insulin as compared to animal species insulin.[12,13] Impaired recognition of hypo-glycemia has been reported in patients whose therapy is changed from animal to human insulin.[14,15,16] Data from Berger et al. demonstrated a difference in the initial symptoms of hypoglycemia between porcine and human insulin. Fifteen initial symptoms with porcine insulin were more often adrenergic (i.e., sweating, hunger) versus "neuroglycopenic" (i.e., anxiety, unrest, confusion, dizziness, difficulty with concentration, paraesthesia, visual disturbances) with human insulin. Results from the Diabetes Complication Study showed that "human insulin use does appear to be associated with reduced awareness of hypoglycemia in those whose blood glucose is relatively poorly controlled."[16]

Based on the information presented, switching the brand or species type of insulin may cause a change in the kinetics, immunogenicity and/or side effect profile of a given patient. Transferring patients from one type of insulin formulation to another may create glycemic instability and subject the patient to an increase or decrease in the incidence of local or systemic allergy, serum insulin concentration, and serum antibody concentration. Transferring patients from one formulation to another may require a dosage adjustment and therefore should be done under medical supervision.

LEGAL LIABILITY ISSUES

The issue of legal liability for pharmacists who sell insulin products cannot be ignored. In fact, the pharmacist may be confronted with more potential legal risks by selling insulin than by dispensing prescription drugs. This greater potential arises because of the complex clinical implications of the product, the fact that there are so many different insulin products and the fact that it is an over-the-counter product for which patients often rely upon the pharmacists' professional judgment and advice.

Theories of Liability

Legal liability risks to a pharmacist may primarily arise from two theories: negligence and breach of warranty. Under negligence, a patient may sue a pharmacist for failing to act (or not act) as a reasonably prudent (or ordinary) pharmacist would have acted under the circumstances. Establishing negligence requires a patient to prove: 1) that the pharmacist owed the patient a duty; 2) that the pharmacist breached that duty because of a substandard act or omission; 3) that the substandard act caused the injury; and 4) the injury and amount of damages. The breach of warranty theory arises from the fact that the sales transaction constitutes a contract between the pharmacist and the patient. Under this theory a patient may sue because of an oral, written or even implied assertion of promise by the pharmacist which the patient relies upon to his or her detriment.

Potential Liability Situations

Liability can result from selling the patient the wrong insulin. For example, in one case a pharmacist was determined negligent when he sold the patient Lente insulin instead of Semilentre insulin, which the patient had requested.[17] Breach of warranty would have been equally applicable, since the patient could have established that the pharmacist breached the terms of the contract by supplying the wrong product which caused the patient's injury. In a similar case, a pharmacist was liable under negligence for selling the patient R-U-100 insulin instead of the N-U-100 insulin requested.[18]

Issues of liability may also arise because of the pharmacist's advice or lack of advice to the patient. For example, assume a patient wishes to switch insulins and consults with the pharmacist about the switch. Under either theory of liability the pharmacist has a duty to render proper professional advice. That advice at a minimum should include reference to the warning statements which are required on insulin labeling which provide: "Warning: Any change of insulin should be made cautiously and only under medical supervision," and "Changes in refinement, purity, strength, brand (manufacturer), type (regular, NPH, Lente, etc.), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage."

Thus, the pharmacist should never assume a switch in insulin is minor, even a switch from the same brand of human semi-synthetic insulin to human rDNA insulin. The patient should always be advised of the warning and the need to consult a physician.

The liability of a pharmacist becomes less clear when the patient does not seek the pharmacist's advice, but purchases the insulin at the pharmacy. For example, a patient who has been using Novolin human semi-synthetic insulin purchases Novolin human rDNA insulin, not realizing the the company has discontinued the semi-synthetic insulin and phased in the rDNA insulin. In its literature the company states only that no change in dosage or daily regimen should be required. It may be possible that in some patients a change will be required. Although the risk of liability to the pharmacist is low, risk does exist and it is a simple exercise in risk management and professional service to advise all patients of this change in Novolin. In any situation where the pharmacist knows, or has reason to know that a patient may be switching insulin, the pharmacist should warn the patient, regardless of whether the patient seeks the pharmacist's advice.

CONCLUSION

The pharmacist is in the unique position of interacting with diabetic patients on a daily basis. Pharmacists should make every effort to become knowledgeable about the different insulin products and supplies available to patients and exercise that knowledge through patient counseling. Patients should be educated on the signs, symptoms and treatment of hypoglycemia and should be cautioned not to switch insulin without medical supervision.

References (18) available upon request.

About the authors: Lenore T. Coleman, Pharm.D., is Chief of Ambulatory Care Pharmacy Services at the V.A. Medical Center in Sepulveda. Richard R. Abood, J.D., is a Professor of Pharmacy Administration at the University of the Pacific School of Pharmacy, Stockton, CA.

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DICKINSON'S PHARMACY

TOTALLY INVISIBLE PHARMACY

"I mean, what do we pay our dues to APhA and NARD for, if pharmacy can't get into the public discussion of health care? It's like we're totally invisible as a profession."

That complaint by Larry Wolfe, owner of Hathaway Pharmacy in the Philadelphia suburbs, struck a chord. He said he's just watched one talk show too many without a pharmacist among panelists from medicine, insurance, government, consumer activists, nursing, etc.

"Could it be," I asked Larry, "that the producers of all these programs don't see pharmacy as being part of the problem?"

"If we beat on their doors hard enough and often enough, they wouldn't dare turn us away," he retorted. Then he turned me away—something more important, a customer, had come into view—and he got off the phone abruptly.

When it's all over—not this year, but maybe next—will pharmacy again be where it has so often been left in the past: holding a "done deal" that it doesn't like?

Larry's complaint is an old and frequently expressed one, only now it has a new urgency.

The future of health care in America is being debated, and minds are getting locked into prideful, defensive positions that may ultimately be unnecessarily rigid.

When it's all over—not this year, but maybe next—will pharmacy again be where it has so often been left in the past: holding a "done deal" that it doesn't like?

If pharmacists pay their dues to have their national associations fix everything without their own direct participation, what are those national associations in fact doing for their money?

I took this question to the American Pharmaceutical Association, where director of government relations Bill Hermelin took the call.

He agreed that pharmacy as a whole has not yet "got its act together" so far as the public debate on the broad structural issues of national health policy is concerned.

But it's dead wrong, he said, to think that pharmacy is "invisible" in government—the profession had major and successful input on the Medicare Catastrophic Act a few years ago, and more recently on OBRA '90 (Omnibus Budget Reconciliation Act), which is currently being felt through Medicaid drug utilization review and counseling provisions, among other impacts.

But the critics are right, Hermelin conceded, in that pharmacy successes tend to occur only in focused pharmacy-dominated arenas, not the broad health policy "structural" arenas.

At the recent Ohio State Pharmaceutical Conference, he and panelists from the American Society of Hospital Pharmacists and the American Society of Consultant Pharmacists agreed that a more aggressive posture is needed by the profession on broad health policy.

Hermelin believes that the profession at the national level has to decide whether its voice will be injected into broad health policy discussion by one representative organization (such as the Joint Commission of Pharmacy Practitioners), or by each of the existing national associations.

This is currently being considered by all the organizations on an urgent basis, so that pharmacy is not left behind.

Hermelin has some other pertinent observations to make on the issue. For example, much as the Larry Wolfes of pharmacy may lament pharmacy's absence from the debates about health care, more health care providers are (like pharmacy) left out than are included.

Podiatrists, ophthalmologists, dentists, long-term care facilities, paramedics, psychiatrists, emergency clinics, etc., all are frustrated in adding their contributions.

And if—as we all believe—pharmacy's contributions ought to be recognized as being able to make a major impact on the rate of cost escalation in other sectors, then part of the blame for that not being more widely accepted lies with manufacturers.

Even though belated efforts are now being made by industry to spread the word about the positive benefits of pharmaceuticals, companies are far from unanimous about how much to say and who to say it to.

One of the reasons for this muffled tower of pharmaceutical Babel is the undeniable fact that hardly anybody can agree on what to say. Is the drug bill itself too high? Can pharmacists cut its cost through DUR and counseling? Which companies would lose if they did? Why should they pay for that message? Is the drug bill in fact too low, vis-a-vis the bill for needless surgery and wasteful lab tests? What is the cost of prescriptions never filled, and who pays?

Such questions—like Larry Wolfe's complaint about the "invisible pharmacist"—have been around a long time. What's different now is that everybody seems to be waking up to the need for urgent solutions, so that pharmacy can take its rightful place in the health care reform "structural" debate.

This is where you come in. Don't close your involvement when you close the flap on the dues envelope you send to your national association.

Put your own dollars to work as well, by spreading the pharmacy cost-effectiveness message. You can do this with in-store posters, letters to the editor, public service announcements on local radio or television, speeches to Rotary and other civic groups, and even with the remark, "Think what your health might cost if you didn't take your medicines!" whenever you deliver a filled prescription.

All such efforts to build pharmacy help at the same time to build public opinion and hasten the day when pharmacy takes its rightful place on the platform of the national health debate.

When that finally happens, a lot of people will be pleasantly surprised to discover what pharmacy can do.

This feature is written and presented by Jim Dickinson on a grant from "Dickinson's Pharmacy–The Independent Voice," a professionally stimulating monthly newsletter, available for $45 a year plus your retail pharmacy's label from Ferdic, Inc., P.O. Box 367, Las Cruces, NM 88004-0367. NCPhA accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of NCPhA.

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REPORT OF THE UNC SCHOOL OF PHARMACY

Presented to the North Carolina Pharmaceutical Association
May 24, 1992
By Tom S. Miya, Ph.D., D.Sci., Dean

I bring greetings from the UNC School of Pharmacy to this 112th Annual Meeting of the North Carolina Pharmaceutical Association. This is my last report to you, and it brings back memories of my first meeting and the gracious reception in 1977. I want to take this opportunity to thank all of you for the support you have given the School and its students during the years of my tenure.

Our students continue to get better, and our faculty continue their successful quest for excellence. The 1991-92 matriculating class of 163 students were selected out of more than twice that number of truly qualified applicants whom we would like to have accepted. Their grade point averages were better than ever and represented seventeen high school valedictorians/salutatorians. The three classes number 478 students; women enrollment number 329 or 70%. Minorities number 21 or slightly over 4%. We need to do better. Our Pharm.D. program has an enrollment of 30. Graduate students, fellows, postdoctoral students and visiting scholars add almost another 100 individuals. I have never seen a brighter, more active group.

For the School, it has been another banner year! I am proud of our faculty and what they continue to accomplish. We claim ownership of your president, Dr. Betty Dennis, the first woman to hold this office in well over a century. She was the recipient of the School of Pharmacy Alumni Association Distinguished Service Award. Pam Joyner, alumnus and clinical faculty, became president of the Pharmacy Foundation, Inc. Al Lockamy was the recipient of the School's Distinguished Service Award. Fourteen UNC faculty became Board Certified Pharmacotherapy Specialists. What is remarkable is that this first certification examination, which had 190 applicants, passed 139. This means that over 10% of Board Certified Pharmacotherapy specialists are UNC School-affiliated. Recently certified as a Nutrition Specialist is another one of our faculty, and another has been a Board Certified Specialist in Nuclear Pharmacy for a number of years.

This year saw the first Kenan Professorship in the history of the School conferred on one of our faculty. Dr. K.H. Lee is an internationally known scientist from whose laboratory emanates at least one invention disclosure a month. Most are in the area of antitumor and anti-AIDS compounds. One antitumor compound, having passed all preclinical evaluations with flying colors, will be introduced into clinical trials this year under licensing to a pharmaceutical company. An additional antitumor compound will follow, pushed by NCI. Over twenty other antitumor compounds are in second-tier testing at the National Cancer Institute. Negotiations are currently underway with a pharmaceutical company for the further development of an anti-AIDS compound.

The Order of the Golden Fleece, as you UNC alumni will remember, is the oldest and highest honorary society to recognize a select group of individuals for their contribution to the University community. Dr. B. Wesley Hadzija pulled off another first in the history of the School of Pharmacy by being inducted into this select group.

On the national front, Dr. Dennis Williams was selected as the American Pharmaceutical Association's Outstanding Academy of Students of Pharmacy Chapter Advisor. Tom Thutt was chosen as the National NARD/Syntex Preceptor of the Year. This follows on the heels of Steve Wilson's selection for this award in 1989. Fred Eckel was the recipient of the Kurt Kleinmen Lecture Award from the Montefiore Medical Center in the Bronx, New York. He was also keynote speaker at the Philippine Society of Hospital Pharmacists and addressed a similar group in Cologne, Germany. Dr. George Dukes was elected chair-elect of the APhA Academy of Pharmaceutical Research and Science Section on Clinical Sciences. He is also serving on the G.I. Drugs Advisory Committee of the FDA. Dr. Joe Norwood will chair the Pharmacy Administration Section of AAPS. Dr. Jane Millen has been appointed for a three-year term to the American Chemical Society Long-Range Planning Committee. Representing the Research Triangle Park Foundation and the North Carolina Biotechnology Center, I was fortunate enough to be invited to join Governor Martin and his delegation in Tokyo to present a seminar to about 100 representatives of Japanese high-tech industries aimed at attracting some of their operations to North Carolina. Currently 120 Japanese companies are in North Carolina.

In other activities, Marily Rhudy, immediate past president of APhA, was on campus in April as the W.J. Smith Practitioner in Residence. This charming, knowledgeable and forward-looking pharmacist gave all of us a look at where we're headed. From the letter Dean Cocolas received from Marily I quote, "The students at UNC reaffirm in my mind that this profession is firmly positioned for the future. Their energy and enthusiasm is most obvious but I also found them to be conversant on issues of importance to our profession.

"No other school of pharmacy that I have visited recently offers the range of opportunities that the University of North Carolina does, for active student involvement in professional associations and fraternities."

Also in April, Dr. Robert L. Talbert of the University of Texas, was on campus to deliver the second annual Howard Q. Ferguson Memorial Pharmacotherapy Lecture. Programs such as these expand student and faculty awareness of innovative contemporary practice and scientific issues.

A focus on pharmacoeconomics and policy is developing between the Division of Pharmacy Administration and the Department of Health Policy and Administration, School of Public Health. Major funding has been received from the Burroughs Wellcome Company for this endeavor for which we are thankful. The Laboratory for Molecular Modeling is proceeding rapidly to national recognition. This venture, housed in the School of Pharmacy, is supported by many collaborators both on and off campus. Recent gifts from IBM to accomplish its mission are much appreciated and add another dimension.

On the educational front, Dr. Christine Hanson received the latest of a long School track record of competing successfully for AACP GAPS grants (Grant Awards to Pharmacy Schools) to investigate means of counseling those who are illiterate and otherwise impaired. Steve Caiola's preceptor training concepts, developed through a GAPS grant, are recognized nationally and are currently being used by most schools of pharmacy. The School has received the largest number of such grants as well as the largest amount of funds from this source since inception of these awards in 1981. Recently announced by the American Association of Colleges of Pharmacy is their Preceptor Development Advisory Group. Albert F. Lockamy and Thomas R. Thutt from North Carolina are two of the four selected nationally. Both are UNC School of Pharmacy Master-Teachers for our preceptors.

The year has been a year of self-evaluation. The strenuous development of the School's Working Plan concurrent with University Planning was followed by continuing the development of our Strategic Plan which is yet to be completed. Our Graduate Program self-evaluation and external site visitation and the American Council on Pharmaceutical Education self-evaluation and accreditation site visit sapped much of the faculty's energy. Hopefully, we are better for it. It goes without saying that as we strive for excellence and added recognition, we ask more and more critical questions of ourselves.

I leave my tenure as Dean not entirely satisfied with what has been accomplished. However, the new Dean will find our School a little more developed than it was in 1977. The role which each of us play in organizational units is to leave it just a little better off than it was. My personal thanks to each of you for the assistance you have offered and will continue to offer as the School heads into the 21st Century.

REPORT OF THE CAMPBELL UNIVERSITY SCHOOL OF PHARMACY

Presented to the North Carolina Pharmaceutical Association, May 24, 1992

By Ronald W. Maddox, Pharm.D., Professor and Dean

The faculty of the School of Pharmacy consists of thirty full-time faculty members. The School also has a cadre of two-hundred and seventy volunteer and adjunct faculty members who serve as preceptors in community, institutional, and industrial training sites.

Our faculty continues to be very productive in teaching and scholarly activities. They have published numerous articles in state and national journals, and submitted grant proposals to state, federal, and private agencies. We have received funding for eight proposals and two federal research requests are pending. These federal grants, which total $221,000, are awaiting final funding decisions by the National Institutes of Health. We have also provided over forty professional presentations.

Our students have been involved in a wide range of professional activities. During the spring break four students attended the American Pharmaceutical Association (APhA) Annual Meeting in San Diego, California. Virginia Clay, a second year student, received one of four national student research awards. She will implement a wellness program on campus for students. The Campbell University Chapter of Kappa Epsilon hosted the Regional meeting of their organization. Eighty-five women from seven chapters across the East Coast attended the conference on campus.

This year the School reached a new high in enrollment of 270 students. We continue to accept an entering class of sixty-five students from a large applicant pool of greater than five applicants per position. Another interesting note is that the Class of 1995 consists of 51% males.

The Campbell University pre-pharmacy program had a great year with in excess of 220 students. As the pre-pharmacy program has grown, the percentage of Campbell students accepted to the School of Pharmacy has increased from 11% in 1986 to 58% in 1991.

In cooperation with the Woman's Auxiliary, the School of Pharmacy scheduled a mobile mammogram unit for two visits to campus. Campbell University assisted in this endeavor by sending out letters in each employee's paycheck, asking them to take advantage of this opportunity. Many of the women had never had a mammogram before!

Graduation weekend was especially exciting this year. Sixty-one graduates received their diplomas. Thomas D. Beard, Vice President Sales, Amgen, Inc., presented a superb hooding address. John Henley was awarded an honorary degree by the University for service to the state through the North Carolina Association of Independent Colleges and Universities.

In February, we completed phase I of the School of Pharmacy's Building Program, with in excess of $1,200,000. We are now working on the phase II goal of $450,000. These funds will enable us to complete and equip the new pharmacy addition. We will also have sufficient funds to renovate the Science Lecture Hall.

In summary, this year has been another exciting and productive year in the history of the Campbell University School of Pharmacy: I take this opportunity to thank the pharmacists of North Carolina for helping to make this possible.

PINETOPS PHARMACIST ATTENDS NATIONAL SYMPOSIUM

Johnny L. Hogg, a practicing pharmacist at Service Drug Store in Pinetops, was among 12 independent pharmacists in the United States who recently attended a Retail Pharmacy Symposium in Kansas City.

The meeting, sponsored by Marion Merrell Dow Inc., was designed to provide a forum in which retail pharmacists could discuss the unique challenges facing the profession in the future. Partnering with the retail pharmacists, Marion Merrell Dow Inc. hopes to improve customer satisfaction by meeting pharmacists' needs as they provide quality services and products to the patients they serve.

Headquartered in Kansas City, Missouri, Marrion Merrell Dow is a global pharmaceutical company that focuses on the discovery, development, manufacture and sale of prescription and over-the-counter pharmaceutical products. The company markets more than 140 products, principally in North America, Europe and the Pacific Basin.

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Community Pharmacy Management Program

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July 24-31, 1993

For the ninth consecutive year APhA is sponsoring an executive-level training program in community pharmacy management. The APhA/SmithKline Beecham Community Pharmacy Management Program is an intensive, seven-day program designed to advance pharmacy practice by improving the management knowledge and skills of community practitioners. This year's program is being hosted by the University of Wisconsin in Madison, Wisconsin from July 24-31, 1993.

To obtain application forms or additional information you may call the NCPhA office 800-852-7343 or Ann Sullivan at APhA at 202-429-7548

Deadline for applications is February 15, 1993.

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NATIONAL PRACTITIONER DATA BANK

Rodney B. Davis, J.D.

The National Practitioner Data Bank (Data Bank) is a federal government creation established by the Health Care Quality Improvement Act of 1986 and expanded as part of the Medicare and Medicaid Patient Program Protection Act of 1987. The Data Bank was established in an effort to improve the quality of medical care in the U.S. by encouraging health care practitioners, including pharmacists, to identify and discipline those who engage in unprofessional behavior and to restrict the ability of incompetent practitioners to move from state to state without disclosure or discovery of their previous incompetent performance. The Data Bank accomplishes this purpose by serving as a clearinghouse for information concerning medical malpractice payments and adverse actions taken by licensing entities, health care entities and professional societies.

The law requires that when an insurance company, self-insurer, or person or entity makes a medical malpractice payment on behalf of a health care practitioner as a result of a written demand or court judgement, such payment must be reported to the Data Bank and the appropriate state licensing agency. A failure to make such a report could result in assessment of a civil money penalty up to $10,000.00. Medical malpractice payment reports are only intended to alert licensing agencies that there may be a problem with a practitioner's competence and should not be construed as creating a presumption that malpractice has occurred.

In addition to receiving medical malpractice reports, the Data Bank also received "adverse action" reports from various state licensing agencies. Licensing agencies such as the North Carolina Board of Pharmacy are required to submit reports within thirty days of the date disciplinary action is taken. Such action includes revocation, suspension, censure, reprimand, probation or a surrender of license. Reportable actions must be based on reasons relating to professional competence or conduct which affects or could adversely affect the health or welfare of a patient. Licensing agencies must report revisions to their actions such as enforcement of active suspension due to violation of probationary terms as well as changes effected by court order.

Access to Data Bank information is restricted to hospitals and other health care entities, state licensing boards and professional societies. A health care practitioner may request information concerning his or her own file. Plaintiffs or their attorneys are only able to access data bank information in medical malpractice actions against a hospital when evidence is submitted which reveals the hospital failed to make a required query of the Data Bank about a practitioner who is named in the action. Medical malpractice insurers do not have access to the Data Bank. Data Bank information is confidential and should only be used by authorized individuals during the course of conducting professional review activities.

The Data Bank is administered by the U.S. Department of Health and Human Resources. Regulations governing the operation of the Data Bank can be found in the Federal Register.

Rodney B. Davis, J.D., is an associate with Bailey & Dixon, a Raleigh law firm.

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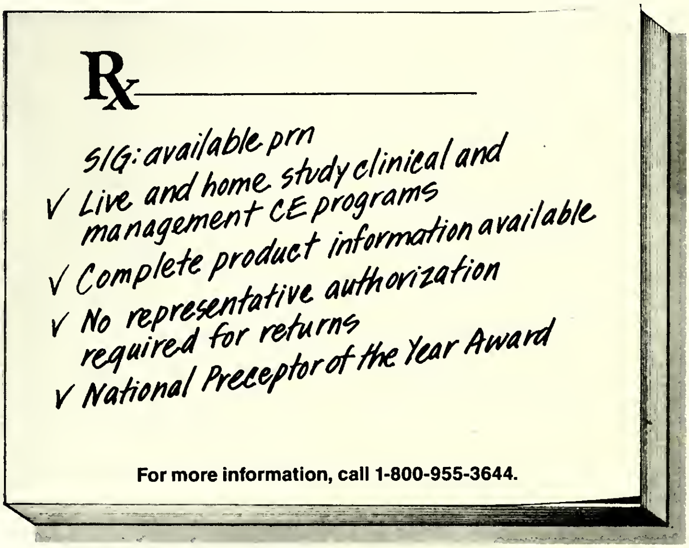

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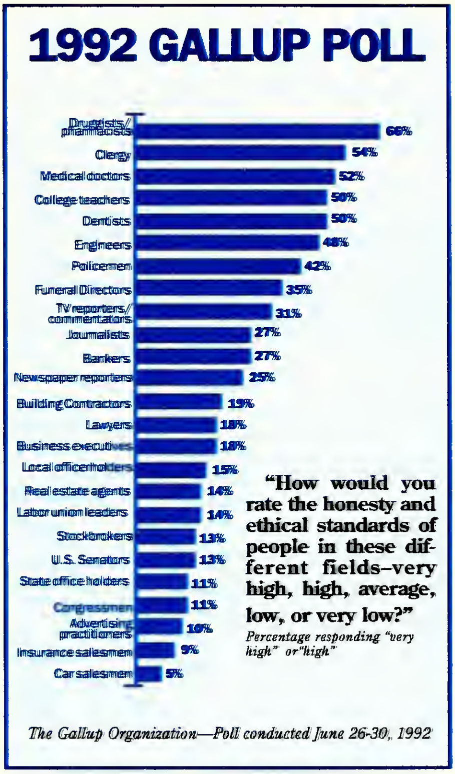
ONCE AGAIN PHARMACISTS TOP GALLUP POLL

For the fourth consecutive time, consumers responding to a Gallup Organization poll rating the honesty and ethical standards of a long list of professions have given pharmacists their number one ranking, and their highest rating to date among all professions in the survey.

The 12 point margin over members of the clergy for the top position on the Gallup Poll is the highest in the poll's history, according to the Gallup Organization, and was one of only two categories that received substantially higher ratings—an increase of 6 percent—compared to the 1991 poll. College teachers' ratings climbed 5 percent over last year. "The American public continues to hold pharmacists in their 'honesty and ethical standards,'" said the Gallup Organization. "Two-thirds of Americans feel that pharmacists demonstrate high or very high standards." Elected officials in federal and state offices received their lowest rating in 16 years of polling on the subject, said the Gallup Organization.

Interestingly, young adults rated pharmacists even higher than individuals over age 65. Among young adults, 72 percent rated pharmacists high or very high, and 58 percent of Americans over 65 gave pharmacists the top two ratings.



"How would you rate the honesty and ethical standards of people in these different fields–very high, high, average, low, or very low?"

Percentage responding "very high" or "high."

The Gallup Organization—Poll conducted June 26-30, 1992

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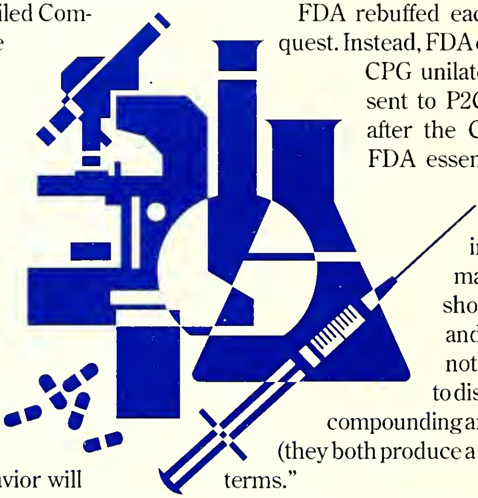
THE CONTROVERSY CONTINUES: FDA & PHARMACY

by Shelly Schluter

Pharmacies have been an integral part of American health care for many years. For decades, pharmacies have compounded medications, pursuant to physicians' prescriptions, for their patients.

The task of regulating pharmacy compounding has been performed by the states. The federal government has not intervened. Until now.

On March 16 of this year, the Food and Drug Administration (FDA) unveiled Compliance Policy Guideline (CPG) 7132.16. This document imposes significant new restrictions on compounding by pharmacists.



The CPG identifies nine prohibited categories of conduct; deviation from any element places the pharmacist at risk of FDA enforcement action. These nine categories are rather vague. Employing such terms as “inordinate” and “regularly,” the CPG forces pharmacists to guess what behavior will be deemed objectionable by FDA. The consequences of guessing wrong can be enormous. During a recent speech, one of FDA's top enforcement officials said, “As for retail pharmacies/pharmacists who will continue to perform one or more of the nine actions listed in the CPG, and thus manufacture unapproved new drugs, they should know that they may be prosecuted.”

Not surprisingly, the CPG has been rather controversial. Many pharmacy groups have asked FDA to clarify its policy and explain what the CPG means. Thus far, no clarification has been offered.

This intolerable situation was entirely avoidable. Professionals and Patients for Customized Care (P2C2), a non-profit organization formed to protect the rights of pharmacists, believes that a federal law, the Administrative Procedure Act, required FDA to solicit comments before issuing the CPG. In any event, P2C2 sent a letter to FDA last December asking for a chance to discuss any new guidelines before they were issued. Other organizations, including the American Pharmaceutical Association, also requested that FDA open a dialogue with pharmacists before announcing a new policy.

FDA rebuffed each and every request. Instead, FDA chose to issue the CPG unilaterally. In a letter sent to P2C2 three months after the CPG was issued, FDA essentially said it felt there simply was no need for any input from pharmacists on how they should be regulated and said, “FDA does not think it relevant to distinguish between compounding and manufacturing (they both produce a drug) or to define terms.”

The CPG is bad enough. Yet FDA has gone even further: it now claims that all compounded drugs are illegal. The CPG itself says compounded drugs are not exempted from the new drug provisions of the Federal Food, Drug and Cosmetic Act (The Act). This means FDA believes each compounded drug must be the subject of an approved new drug application (NDA). It is estimated that it takes ten years and $200 million to get an NDA. But without an NDA, according to FDA, the compounding pharmacist has broken federal law.

FDA's position was even more clearly stated in a warning letter sent to a pharmacist this June. An FDA district director wrote, “a drug product compounded in a pharmacy without FDA's approval is an unapproved new drug subject to all the provisions” of federal law.

Violating these provisions can lead to severe penalties: product seizure, court injunction and criminal prosecution.

At the end of August, FDA made bolder attempts to restrict the pharmacists' ability to compound. The FDA issued warning letters to pharmaceutical supply companies. One letter said the supply company is in violation of federal law because the chemicals they supply to pharmacists "are drugs offered for use by registered pharmacists in compounding prescriptions." The letter further stated, "the compounded drugs are regarded to be new drugs within the meaning of Section 201 (p) of the Act, and no New Drug Applications have been approved for these compounded drugs." The chemicals the FDA charged to be in violation of the act are: Progesterone, Metaproterenol Sulfate, Progesterone Wettable, Sucralfate Powder, Prednisone, Cromolyn Sodium and Albuterol Sulfate. In another letter to a chemical supply company, FDA gives a list of the only chemicals that the FDA says can be legally sold to pharmacists for compounding. The list includes: Bacitracin, Bacitracin Zinc, Erthromycin, Hydrocortisone, Hydrocotone Bitartrate, Neomycin Sulfate and Polymyxin B Sulfate.

Historically, the pharmacy profession has been well respected by the public and has an excellent history of safety. We strongly believe that FDA's intrusion into this area was unnecessary and unwarranted. We reject FDA's assertion that a pharmacist commits a federal crime every time he or she compounds and that a chemical company is in violation of federal law because it supplies chemicals to pharmacists who compound. And we are distressed that FDA rejected all efforts to develop its new pharmacy policies without guidance from the individuals most affected—the pharmacists of America. We therefore urge FDA to withdraw its CPG and its statements that compounded drugs are illegal, and initiate a dialogue with the entire pharmacy community.

Shelly Schluter is the executive director of Professionals & Patients for Customized Care (P2C2). P2C2 is an organization consisting of pharmacists, physicians and patients, who are actively working to keep FDA regulations out of the practice of pharmacy. If you have any questions, or would like to become a member of this organization to help defer the cost of the lawsuit for all of pharmacy, please contact Shelly at the P2C2 office 713/933-8400, or write to: P2C2, PO Box 1365, Sugar Land, TX 77487.

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PREVENTING DISPENSING ERRORS

by Carol Fisher, R.Ph., Director of Adjudication and Legal Support Services

Reprinted from the *Texas Board of Pharmacy Newsletter* **Vol. XVI, No. 2**

Pharmacists spend many long hours in their pharmacies, flawlessly performing, on a daily basis, thousands of functions involved with dispensing prescriptions. The attention, honesty and integrity of pharmacists has earned the profession the respect of the public.

However, we are all too aware that pharmacists are human, and all humans make mistakes. Often these mistakes are of no real significance and we can learn from them and move on. But please remember, one of the pharmacist's primary duties is to dispense prescriptions accurately. If a mistake results in a dispensing error, serious health consequences may result. With this in mind, let's review some of the reasons dispensing errors occur and ways to avoid them.

Factors Causing Dispensing Errors

External Factors

These types of factors arise from causes beyond the pharmacist's control, such as:

(1) prescriptions written with illegible handwriting;

(2) multiple prescriptions on one prescription blank, including preprinted prescriptions with multiple drugs and directions for use;

(3) incomplete, incorrect, or ambiguous written orders, or instructions;

(4) poorly transmitted verbal orders;

(5) drugs with look-alike or sound-alike names;

(6) poor packaging or labeling of drugs by industry; and

(7) prescription information being relayed through a third party (e.g., a prescriber's designated agent who may not be completely informed or knowledgeable about the prescriber's directions or intent.)

Internal Factors

These types of factors are found in the working environment, some of which are beyond the pharmacist's control, such as:

(1) inadequate staffing (e.g., not sufficient "overlap" of pharmacists during shift change, one pharmacist attempting to dispense too many prescriptions on a routine basis);

(2) heavy workload (e.g., periods of the day when "peak" activities occur);

(3) long working hours (e.g., one pharmacist working 13-hour shifts);

(4) interruptions (e.g., pharmacist stopping to answer the telephone or help a customer);

(5) distractions (e.g., TV and/or radio playing in the work area, "traffic" throughout the prescription department);

(6) inadequate internal controls (e.g., no "checking" mechanism in place); and

(7) poor organization of prescription department (e.g., inadequate space, and poorly designed work area).

Personal Factors

These types of factors are under the control of the pharmacist, such as:

(1) lack of concentration

(2) lack of knowledge (e.g., pediatric doses);

(3) mental, chemical, or physical impairment;

(4) stress;

(5) attitude (e.g., uncaring, thoughtless, robot-like performance);

(6) inadequate supervision of supportive personnel (e.g., not checking the labels produced by support personnel and pharmacy personnel handing prescriptions to customers without double checking the patient's name and doctor's name); and

(7) sloppy work habits (e.g., clutter, not promptly recapped opened containers, prepackaging "fast movers" without labels).

Suggestions on Avoiding Dispensing Errors

(1) First and foremost is to recognize the factors that cause dispensing errors and work toward eliminating all causes (e.g., call the physician regarding any questions about the prescription).

(2) Check the original label against the actual prescription, not against a computer generated prescription. Then institute the "triple check plus two" method into your dispensing pattern (i.e., check the name and strength of the drug when taking the drug off the shelf, check the name and strength of the drug after affixing the label to the container—then check the NDC number on the computer screen or printout against the NDC number on the stock label and finally, take the prescription out of the bag and review it visually while discussing it with the patient).

(3) Repeat the patient's and doctor's name to the person picking up the prescription (i.e., make every effort to make sure that each patient receives their medication and not someone else's).

(4) When patients order refills, record the prescription number, patient's name and drug name to allow cross checking.

(5) When possible, have another person check your work, especially for medications with a high risk of error (e.g., if supportive personnel are used, check each other's work—but remember, when the pharmacist attaches the prescription label, the pharmacist assumes total responsibility for the accuracy of the prescription).

(6) Limit the number of repacks (e.g., more than one strength of a particular drug should not be prepackaged).

(7) Separate drugs with similar looking or sounding names (e.g., put drugs such as Isordil and Inderal, Lasix and Lanoxin, Dilantin and Dyazide, in different parts of the prescription department).

(8) Affix colored stickers on stock bottles which will "flag" the expiration date of the drug (e.g., put a red spot on every drug which will soon expire).

(9) Know the drugs (e.g., pediatric doses, directions for use, etc.).

(10) Know the patients (e.g., if you know a particular person is an infant, you know the dosage will be different).

(11) Consult with patients (e.g., when explaining the directions for use, a pharmacist should look at the label and the contents and re-check for errors in labeling or packaging—better to find the error at the time of consultation, than later when the patient has left the pharmacy).

(12) Fight monotonous routine (e.g., look for more efficient and effective ways to practice pharmacy, subject every procedure to a regular review and assessment, and add variety through alternative mechanisms).

(13) Don't get in a hurry.

Suggestions On Handling Errors (if one occurs)

To the patient, the correct medication is the only thing that matters. They are not concerned about other patients or about your problems. They are concerned about their own health. Non-pharmacist staff should be trained to immediately refer to a pharmacist all customer contacts concerning possible dispensing errors. No matter how trivial a complaint may appear to be, handle it with concern and discretion. Do not be offhand, flippant, or evasive when handling complaints regarding a possible or actual dispensing error. Consumers want to know the details of the error, because it is a personal concern of theirs—the error happened to them. When contacting the Board's office, many complainants have stated "The pharmacist did not even say, 'I'm sorry.'" Consumers want pharmacists to apologize.

In addition, pharmacists should do whatever is necessary to correct the error, even if it means delivering the correct drug to the patient by taxi. Many times, consumers appreciate economic considerations, such as refunding the patient's money or dispensing the prescription at no charge. Pharmacists should also contact the prescribing practitioner.

In summary, there are many components to the dispensing process and each juncture is susceptible to human error. Of the millions of prescriptions dispensed each year, the number of dispensing error complaints received by the Board is extremely small. However, because of public health consequences, each complaint is taken very seriously by the Board. Pharmacists must be constantly aware of the factors leading to dispensing errors and take whatever steps necessary to eliminate them.

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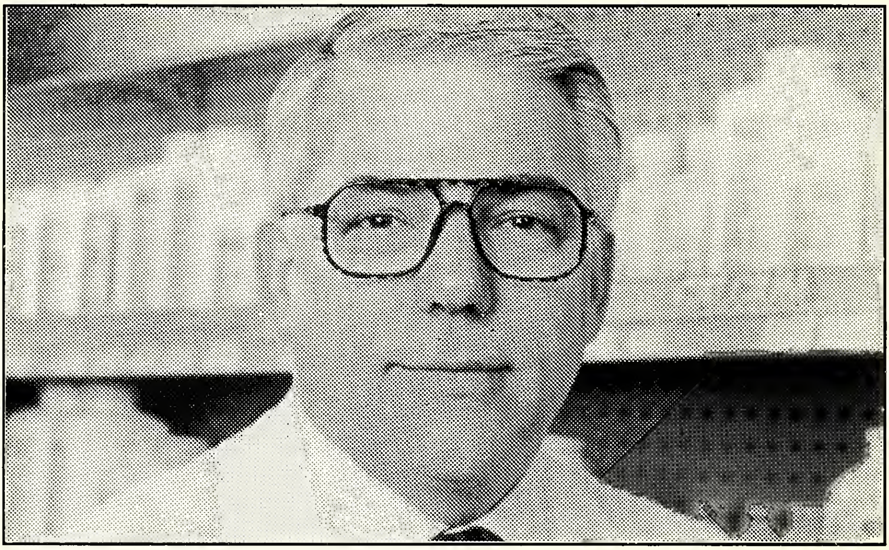

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CORRESPONDENCE COURSE

NEW DRUGS OF 1992
PART II: CARDIOVASCULAR AGENTS

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to identify and discuss new drugs that are active on the cardiovascular system.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. *exhibit knowledge of the pharmacologic classification and therapeutic considerations for each of the drugs discussed:*
2. *select from a list their indications and mechanisms of action;*
3. *identify adverse effects, major toxicities, and drug interactions associated with the drugs; and,*
4. *choose important information when counseling patients on these new drugs.*

Antihypertensives

ACE Inhibitors. There are four new angiotensin converting enzyme (ACE) inhibitors: **benazepril (Lotensin/Ciba-Geigy), fosinopril (Monopril/Bristol-Myers Squibb, Boehringer Ingleheim), quinapril (Accupril/Parke-Davis), and ramipril (Altace/Hoechst-Roussel, Upjohn).** (Table 1)

ACE inhibitors exert their antihypertensive effects by lessening the formation of angiotensin II, a potent vasoconstrictor. Hemostasis is maintained by several mechanisms which adjust to periods when blood flow must be shifted from one area to another. For example, in the "fight or flight" phenomenon, blood must be shunted from the skin and subcutaneous areas to muscles so that the person can respond appropriately. Other times, such as during sleep, a relatively low blood pressure is required.

Angiotensin converting enzyme plays a major role in blood pressure regulation. Briefly, the inactive peptide angiotensinogen is metabolized to angiotensin I is then converted by ACE to angiotensin II. Angiotensin II is a potent vasoconstrictor, and also stimulates the

Table 1
COMPARISON OF NEW ACE-INHIBITOR DRUGS

Generic Name	Trade Name (Mfr)	Availability	Active Metabolite	Frequency of Dosing
Benazepril	Lotensin (Ciba-Geigy)	5, 10, 20 & 40 mg tablets	Benazeprilat	1-2 x/day
Fosinopril	Monopril (Bristol-Myers Squibb; Boehringer Ingelheim)	10 & 20 mg tablets	Fosinoprilat	once daily
Quinapril	Accupril (Parke-Davis)	5, 10, 20 & 40 mg tablets	Quinaprilat	1-2 x/day
Ramipril	Altace (Hoechst-Roussel; Upjohn)	1.25, 2.5, 5 & 10 mg capsules	Ramiprilat	1-2 x/day

adrenals to release aldosterone. This mineralocorticoid increases sodium and water retention to raise blood pressure further.

ACE also catalyzes conversion of bradykinin, the vasodilator counterpart to angiotensin II, to inactive peptides. Normally, bradykinin and angiotensin II and decrease bradykinin, it can be seen that a drug which inhibits it will reduce elevated blood pressure.

ACE inhibitors also influence the body's fluid levels. By inhibiting angiotensin II production, they reduce aldosterone release. Thus, less sodium is retained, more water is excreted, and total body fluids are reduced.

ACE inhibitors act upon the renin-angiotensin-aldosterone system beyond the site of renin influence. Therefore, unlike thiazides and beta-adrenergic blockers, ACE inhibitors lower elevated blood pressure regardless of renin levels. This increases the range of patients for whom they are effective.

The new drugs, like their predecessor enalapril, are prodrugs that are converted to active metabolites following oral administration. As with lisinopril, all four can be administered on a once- or twice-daily dosage regimen.

Adverse reactions most commonly reported include nausea, headache, dizziness, fatigue, and a dry, nonproductive cough. Postural (orthostatic) hypotension, although rare, is reason to advise patients that lightheadedness may occur, especially during the first several days of therapy. The drugs can elevate serum potassium. Individuals with diabetes or renal insufficiency, and those taking a potassium-sparing diuretic (e.g., amiloride, spironolactone, triamterene) are at special risk. Concomitant use of these agents and an ACE inhibitor should be avoided. All products have this warning in their labeling and some contraindicate concomitant use. The same is true for potassium supplements.

Recently, FDA told manufacturers to strengthen the warning that the use of ACE inhibitors by pregnant women should be avoided, and to make it a part of a "boxed warning." The drugs can cause fetal and neonatal morbidity and mortality. Problems include skull hypoplasia, neonatal hypertension, renal failure, and death. Unlike other teratogenic birth defects which occur during the first trimester, the problem with ACE inhibitors is critical in the second and third trimesters of pregnancy.

Calcium Channel Blocker. Felodipine (Plendil/Merck Sharp & Dohme) is a new calcium channel blocker, (CCB) for treatment of essential hypertension. It shares the same mechanism of action for reducing blood pressure as that of other calcium channel blockers.

To explain briefly, smooth muscle cell membranes are comprised of layers of lipid interspaced with protein and carbohydrate. Cell membranes are impervious, thus maintaining osmotic integrity.

Water, ions and other materials enter and leave cells by special transport systems including a system of channels. In their resting state, the cell membrane, being lipophilic and hydrophobic, repels water-soluble ions. When smooth muscle cells depolarize, i.e., receive an electrical impulse and form neurons, the ionic charge on the outside of the membrane changes. This allows specific ions to pass through their channels into the cells.

Two important ions for muscle contraction are sodium and calcium. Sodium ions are smaller so they can enter more quickly. Though the time difference is extremely short, the systems are referred to as the "fast" (sodium) channel, and the "slow" (calcium) channel. The result of calcium entry is contraction.

It is believed that sodium channels provide an immediate electrical impulse to cells to insure a high reliability for contraction. This primes muscle fibers to start the contractile process, assuring that a complete electrical impulse has been received and that conduction and contraction will occur. CCBs retard calcium influx into the cells.

Their mechanism is further explained in that within smooth muscle cells, calcium ions play an integral role in causing contraction. Within the sarcoplasmic reticulum, calcium combines with an endogenous substance (calmodulin in blood vessels; troponin in myocardial tissue.) This combination, in turn, attracts the proteins actin and myosin which, in their resting state, are separated, to slide over each other. With this action, the physical size of the cell decreases, resulting in muscle contraction. So, lessening the influx of calcium ions into smooth muscle cells, e.g., arteries, reduces their contraction.

Felodipine is a member of the dihydro-pyridine group of CCBs. Others include isradipine (DynaCirc), nicardipine (Cardene), nifedipine (Procardia, etc.), and nimodipine (Nimotop). These agents can cause reflex tachycardia during initiation of therapy. The other CCBs verapamil (Calan, Isoptin, etc.) and diltiazem (Cardizem, etc.) incite little or no change in heart rate, but can slow atrioventricular (AV) conduction. Therefore, these two drugs can interact with beta-adrenergic blockers. The dihydropyridines do not slow AV conduction and may be safer for use with beta-adrenergic blockers. All CCBs should be used with caution, if at all, in persons with heart failure.

Felodipine is well tolerated in most patients. Adverse effects include peripheral edema (most common), headache, flushing, tachycardia, palpitations, and postural dizziness. All are related to the drug's vasodilation action. Gingival hyperplasia (overgrowth of gum tissue) has also been reported. CCBs as a group are not likely to increase serum lipid levels like some other antihypertensives such as the thiazides.

Plendil is marketed in 5 mg and 10 mg controlled-release tablets and is taken once daily. The drug is interspersed with hydrophilic agents that hydrate, swell and dissipate, to release active ingredients. Patients should be advised to swallow the tablets whole; crushing or chewing destroys the controlled-release property.

Antithrombotic

Ticlopidine (Ticlid/Syntex). This antithrombotic is indicated for reducing the risk of thrombotic stroke in patients who have experienced stroke precursors, and in those who have had a completed thrombotic stroke. Because there is a risk of life-threatening neutropenia and agranulocytosis, ticlopidine should be reserved for patients who are intolerant of aspirin.

While the exact mechanism of action of ticlopidine is not fully known, it does act differently than aspirin or dipyridamole, the other antiplatelet agents. Formation of a blood clot consists of the aggregation, adhesion, lysis and deposition of platelets to form a hemostatic plug. During this sequence of events, platelets congregate, stick together, break apart and release a number of substances that will catalyze the eventual formation of the permanent clot.

Patients with thromboembolic disorders experience this too often. Preventing platelets from aggregating excessively reduces clot (thrombus) formation. This, in turn, reduces the breaking away of clots (emboli) from their point of formation. Emboli circulate to small blood vessels where they can lodge and block blood flow to the area. If this occurs in the heart, the result is a myocardial infarction; in the brain, a thrombotic stroke.

Aspirin exerts antiplatelet action by acetylating, thereby inhibiting the enzyme cyclooxygenase. This lessens formation of thromboxane A2, a prostaglandin derivative that induces platelet aggregation. Dipyridamole has several activities including inhibition of the enzyme phosphodiesterase. This increases platelet cyclic-AMP levels which stabilizes and renders them less likely to adhere to each other.

Ticlopidine does not affect either enzyme. Rather, it appears to interfere with the ability of platelets to adhere to each other. The net result is inhibition of platelet aggregation. It may also impair platelet adhesion and deposition on previously formed atherosclerotic plaque. A slight inhibition of platelet aggregation is noted in six hours. Maximum therapeutic effect can be achieved after 3 to 5 days of oral therapy.

The results of two large trials with ticlopidine attest to its activity. The Canadian American Ticlopidine Study (CATS) and Ticlopidine Aspirin Stoke Study (TASS) collectively evaluated more than 4000 patients. In persons who experienced a recent stroke, the incidence of a second stroke, myocardial infarction or vascular death was reduced 30 percent compared to placebo. It was significantly better than aspirin in preventing death from all causes of nonfatal stroke. Moreover, ticlopidine appears to be equally effective in both men and women.

There are two important considerations when counseling patients taking Ticlid. First, ticlopidine can cause intense irritation to the gastric mucosa resulting in ulceration and bleeding. The drug must, therefore, be taken with food.

Second, ticlopidine caused neutropenia in 2.4 percent of patients in clinical trials. FDA requires a boxed warning in its package insert stating that it is essential for complete blood counts and white blood cell differentials to be performed every two weeks beginning the second week of therapy through the third month. This corresponds to the period of greatest susceptibility to ticlopidine-induced neutropenia. The manufacturer assures that the blood work is free to patients; the physician must order the tests, however.

Ticlid is marketed as 250 mg tablets. It should be taken twice daily.

Antihypercholesterolemics

Pravastatin (Pravachol/Bristol-Myers Squibb) and Simvastatin (Zocor/Merck Sharp & Dohme).

These new drugs join lovastatin (Mevacor) and are indicated as adjuncts to diet for reduction of cholesterol in patients with primary hypercholesterolemia (Types IIa and IIb). More than 1,000,000 patients to date have been successfully treated with lovastatin, prompting development of the two new drugs. Other similar drugs will undoubtedly join the group in the future.

Both new drugs, like lovastatin, inhibit 3-hydroxy-3-methylglutarl-coenzyme A (HMG-CoA) reductase in the liver. This enzyme catalyzes the rate-limiting step in cholesterol biosynthesis conversion of HMG-CoA to mevalonate. This step in cholesterol synthesis occurs at a point early in its metabolic pathway. Previous attempts at blocking cholesterol synthesis with drugs resulted in blockade at sites further along the path. A previ-

Table 2
COMPARISON OF CHOLESTEROL-LOWERING DRUGS

Drug	LDL	HDL	Triglycerides
Niacin (Nicobid, etc.)	decrease (VLDL)	increase	decrease
Gemfibrozil (Lopid)	decrease (VLDL)	increase	decrease
Lovastatin (Mevacor)	decrease	increase	decrease
Simvastatin (Zocor)	decrease	increase	decrease
Pravastatin (Pravachol)	decrease	increase	decrease
Cholestyramine (Questran)	decrease	none to slight increase	transient increase; return to baseline within 4 weeks
Colestipol (Colestid)	decrease	none to slight increase	transient increase; return to baseline within 4 weeks
Probucol (Lorelco)	decrease	decrease	no effect
Clofibrate (Atromid S)	decrease (VLDL)	no effect	decrease

HDL, high density lipoprotein; LDL, low-density lipoprotein; VLDL, very low density lipoprotein

ously marketed drug, triparanol (MER-29), caused accumulation of intermediate metabolites and, eventually, toxicity. The HMG-CoA reductase inhibitors do not do this. They reduce total cholesterol and LDL-cholesterol production, and elevate HDL-cholesterol levels. Table 2 compares the actions of antihypercholesterolemic agents.

Pravastatin and simvastatin are generally well tolerated. The are contraindicated in liver disease or unexplained, persistent elevations in liver-function tests. Liver-function tests should be performed regularly during the first year of therapy, and periodically thereafter.

Uncomplicated myalgia (muscle aching), myopathy (any muscle disease), and/or rhabdomyolysis (necrosis of muscle) are occasionally observed. Unexplained muscle pain, weakness, or tenderness should be reported to the physician.

There are unconfirmed reports of patients receiving both an HMG-CoA reductase inhibitor and gemfibrozil (Lopid) developing myopathy and renal failure. The mechanism for this interaction has not been identified, nor is there a proven cause and effect relationship. Nonetheless, the manufacturers of both drugs state in their package insert that possible benefits of combined therapy do not outweigh the risks, that there is no assurance that periodic monitoring of renal function will prevent the occurrence of severe myopathy/renal damage, and that combined use should be avoided.

There is concern that use of cholestyramine (Questran) and colestipol (Colestid) may reduce the therapeutic effect of concomitant HMG-CoA reductase inhibitors by binding with them to reduce absorption. Doses of the latter should be given at least one hour before or four hours after bile acid sequestrant resins.

In contrast to lovastatin which should be taken with food to enhance absorption, the newer drugs can be taken without regard to food. Pravastatin and simvastatin are best taken as a single bedtime dose. Timing is important to maximize therapy since the peak time for hepatic cholesterol synthesis is approximately between 2 a.m. and 6 a.m.

A professional development program made possible by an educational grant from

SEARLE

Pravachol is supplied as 10 mg and 20 mg tablets; plans are underway to market a 40 mg dosage strength.

Antianginal

Isosorbide mononitrate (ISMO/Wyeth-Ayerst). Isosorbide mononitrate (hence its trade name ISMO) is the major active metabolite of isosorbide dinitrate. It is indicated for prevention of chronic, stable angina pectoris attacks due to coronary heart disease. It is not approved to abort acute anginal attacks because of its slow (one hour) onset of action. Most of the clinical activity of the dinitrate salt is due to conversion to the active mononitrate metabolite. The claim is made that there is less chance for tolerance to the mononitrate salt, presumably because isosorbide dinitrate induces its own metabolism in some patients.

Tolerance reportedly does not develop as rapidly with the mononitrate as with the dinitrate salt if the dosing schedule is complied with: twice-daily administration with the first dose in the morning and the second seven hours later. This provides a nitrate-free period toward the end of the day which also reportedly minimizes significant rebound/withdrawal effects. Isosorbide mononitrate is marketed as 20 mg tablets.

Patient Advice for the New Drugs

ACE inhibitors. ACE inhibitors can be taken without regard to food. It is best that each dose always be taken with food or always on an empty stomach. Doses should be taken at the same time each day. In the event that a dose is missed, if it is almost time for the next dose, the patient should skip the missed one and resume the regular schedule.

The manufacturer of Monopril states that antacids may reduce absorption, thus lowering serum concentrations. If concomitant therapy is necessary, dosing should be separated by two hours.

ACE inhibitors can cause potassium retention. Salt substitutes should be avoided unless ordered by a physician.

ACE inhibitors can cause angioedema, especially following the first dose and in the facial area. Before taking further doses, patients should inform the physician of signs of angioedema such as swelling of the face, lips, tongue or eyes, or difficult breathing. Other symptoms that should be reported to the physician are persistent sore throat or fever (signs of neutropenia). Women who become pregnant while taking an ACE inhibitor should consult their physician promptly.

Plendil. Although it can be taken with meals, the best time to take Plendil is on an empty stomach with a full glass of water. Doses should be taken at the same time each day. In the event that a dose is missed, if it is almost time for the next dose, the patient should skip the missed one and resume the regular schedule.

The following signs and symptoms should be reported to the physician if they occur: headache, nausea, swelling of the extremities, unusually slow heartbeat, chest pain, unusual tiredness or difficult breathing.

For ACE Inhibitors and Plendil. This medication may cause lightheadedness. Patients should sit or lie down at the first sign of dizziness. They should avoid sudden changes in posture and use caution going up or down stairs, driving, or performing hazardous tasks.

Since systemic sympathomimetics including those in OTC cough, cold or allergy remedies and appetite appeasers (phenylpropanolamine, phenylephrine, ephedrine, pseudoephedrine) may aggravate high blood pressure, patients should obtain advice before self-medicating with them. Topically-applied sympathomimetics reportedly are less involved in this interaction and may be safer than orally-ingested products.

Pravachol and Zocor. Patients should follow a standard cholesterol-lowering diet for this medication to work properly. In the event that a dose is missed, if it is almost time for the next dose, the patient should skip the missed one and resume the regular schedule.

The following signs and symptoms should be reported to the physician if they occur: blurred vision, muscle pain, tenderness or weakness, fatigue, fever, stomach pain, headache, nausea or skin rash.

CONTINUING EDUCATION QUIZ

New Drugs of 1992, Part II: Cardiovascular Agents

1. All of the following are ACE inhibitors EXCEPT:
a. Altace
b. Lotensin
c. Accupril
d. Plendil

2. Ticlid acts by inhibiting:
a. cyclooxygenase
b. phosphodieterase
c. platelet adherence
d. combination of fibrinogen

3. In addition to their primary action, ACE inhibitors also inhibit production of:
a. aldosterone
b. cortisol
c. insulin
d. thyroid hormone

4. Because of the activity referred to in question #3 above, ACE inhibitors can cause:
a. hyperthyroidism
b. diabetes
c. hyperkalemia
d. pheochromocytoma

5. Of the following, which is the most important information to convey to patients receiving a prescription for Plendil?
a. Avoid excessive exposure to sunlight.
b. Do not crush or chew the tablet.
c. This may discolor the urine and/or feces.
d. Do not take antacids with Plendil.

6. Patients receiving a prescription for pravastatin should be advised that the best time to take the dose is:
a. at bedtime
b. before meals
c. on arising
d. after meals

7. The enzyme that catalyzes conversion of antiotensinogen to angiotensin I is:

a. angiotensin converting enzyme
b. angiotensin enzyme
c. HMG CoA reductase
d. renin

8. Plendil is most closely related chemically and pharmacologically to:

a. Calan
b. Isoptin
c. Cardizem
d. Procardia

9. All of the following are true statements about the recently approved ACE inhibitors EXCEPT:

a. like lisinopril, they can be given on a once-daily dosage.

b. like captopril, they are controlled-release dosage forms.

c. like enalapril, they are prodrugs.

d. like previously marketed ACE inhibitors, they affect bradykinin metabolism.

10. Patients receiving which of the following drugs should be advised to have blood tests performed every two weeks for the first three months of therapy?

a. Monopril
b. Plendil
c. Ticlid
d. Zocor

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CONTINUING PHARMACEUTICAL EDUCATION (CPE)

New Drugs 1992, Part II: Cardiovascular Agents

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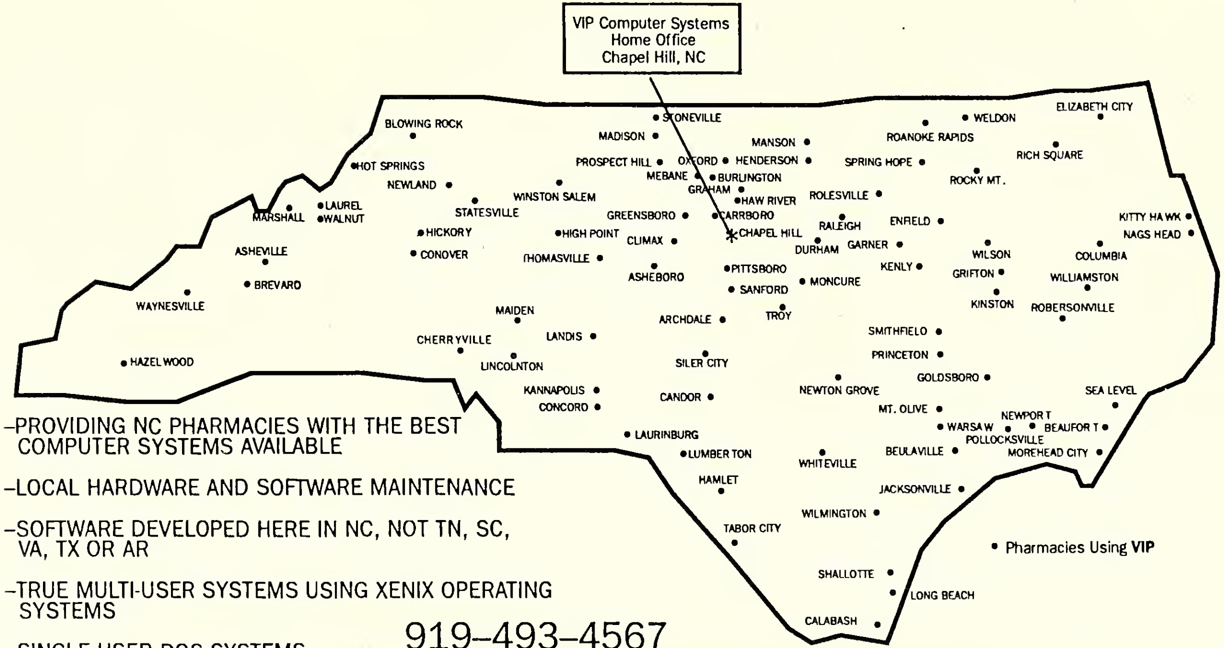

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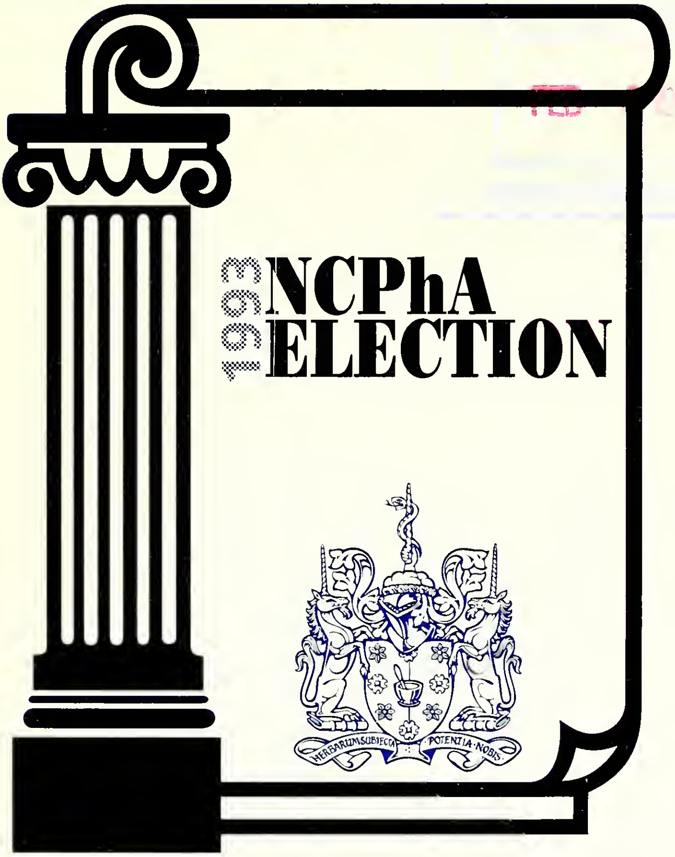

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Important figures in diabetes care

7

Diabetes is the **No. 7** cause of death in the US[1]

1

Diabetes is the **No. 1** cause of new blindness in persons aged 20-74[1]

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1. *Diabetes Surveillance, 1980-1987.* Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes.* Indianapolis, Ind. Eli Lilly & Company; 1987, 6-13.

★ ★ ELECTION '92 ★ ★

INTRODUCING THE NCPHA CANDIDATES FOR OFFICE

Ballots for the NCPhA's 1992 elections will soon be mailed to all Association members. The slate consists of three candidates for president-elect and six candidates for two member-at-large positions on the NCPhA Executive Committee.

Of the candidates running for the two member-at-large positions, the two candidates who receive the greatest number of votes will be elected to a three-year term.

NCPhA members will receive their official ballot in late January. Ballots are to be returned within 30 days of receipt. Ballots will be counted by the elections committee in early March. Results of the election will be published in an upcoming issue of *The Journal*.

Successful candidates will be installed in their new offices in May 1993 during the 112th NCPhA Annual Convention in Morehead City.

The 1991-92 NCPhA Nominating Committee presents the following slate of officers which was approved by the membership at the 112th Annual NCPhA Convention in May 1992.

Biographical data are presented for each candidate. Candidates for positions on the NCPhA Executive Committee were asked to submit a response limited to 150 words or less on: *"What role should the NCPhA play in implementing Pharmaceutical Care?"*

Members of the 1991 Nominating Committee were: Chairman Henry L. Smith, Sarah B. Cobb, Steve Critz, J.A. Hill, Pamela U. Joyner, Wallace E. Nelson, and Thomas R. Thutt.

★ FOR PRESIDENT-ELECT ★

(one to be elected)

Phillip F. Crouch
Asheville

Phillip Crouch is a graduate of the UNC School of Pharmacy. He is owner of Ideal Drug Store in Asheville. As an active member of NCPhA for more than 26 years, Phil has served on numerous NCPhA committees. He has served as a member-at-large on the NCPhA Executive Committee. Phil served as president of the Buncombe County Pharmaceutical Association in 1971. Currently he is a member of the Western North Carolina Pharmaceutical Association, NARD, the North Carolina Retail Pharmacists Association, a member of the Board of Directors of the Pharmacy Network National Corporation and Board Member of the Asheville Merchants Association.

"Did you know that the three wise men were firemen? Well the Bible says they came from 'afar.' What fire do we have to put out now because we have waited too long to attack the issues? Before we can attack any of the coming fires, we must get our finances in shape. If independent retailers start closing because of fires we have not put out yet, such as third party (without our input) pricing, mail order, tier pricing, state employee pricing, etc., do you think with these pharmacists looking for jobs it will be long before hospital pharmacists are paid less, etc? We must all work together or we will surely sink together.

"What is this year's fire? Pharmaceutical Care is described by others as responsible drug therapy achieving definite outcomes that improve a patient's quality of life. These outcomes should be:

1) cure of disease
2) elimination or reduction of a patient's symptoms
3) arresting or slowing of a disease process
4) preventing a disease or symptoms.

"Are we able to do this? Yes. Are we competent to do it now? Maybe. This is where the Association may be able to help by backing us with special programs, proper educational materials and guidance on how to implement such goals. Do we want to do this? Maybe. It means accepting a lot more responsibility, work time and study. Can we get paid for all this extra investment in ourselves? Or, like counseling, do it for free? Can we get the cooperation of the doctors, nurses, etc.? Here again the Association can help us. We need to work with their associations ahead of time to achieve this goal rather than after the fact.

"Let us lead for a change instead of waiting for someone else to tell us what to do (like the Feds with counseling). Great professions lead; others follow. Why not be great!"

Joseph A. Edwards Jr.
Raleigh

Joseph A. "Joey" Edwards is the President of Edwards Pharmacy and Edwards Management Company in Raleigh, and a consultant with the Wake County Public Safety Center. He is a member of the NCPhA and has served on various committees, including his current position as co-chair of the Retail Pharmacy Committee. He is a member of the Academy of Pharmacy, NARD and NC PharmPAC, having served as its president in 1980. He also holds membership in the Wake County Pharmaceutical Association (of which he is a past-president), the UNC General Alumni Association, and the Greater Raleigh Chamber of Commerce.

"The concept of pharmaceutical care is as intimidating to some today as clinical pharmacy was twenty years ago. Yet, today, clinical pharmacy is practiced as effectively in the corner drug store as in the hospital setting because we have dedicated professionals who have always put the patient first. Health care in America is evolving, and it is time for pharmacy to re-invent itself. We have spent enough time identifying the problems. It is time to get into action and formulate solutions. What role should NCPhA play?

1) Define its action plan through efforts of the Strategic Planning Task Force and NCPhA leadership.
2) Be a facilitator in bringing all factions in pharmacy together for consensus.
3) Redefine its commitment to legislative action by creating a well-funded, professionally run lobbying effort and clearly defining its legislative intent.
4) Produce quality continuing education,

materials needed for accomplishing Pharmaceutical Care, and Models of Practice standards.
5) Improve grassroots involvement to unify pharmacists.
6) Be the voice of pharmacy in North Carolina.
7) Restructure its committee system to concentrate the leadership in areas of highest concern.

"Pharmaceutical Care will be accomplished through focus, motivation and diligence. The NCPhA must be the leader."

Jimmy S. Jackson
Raleigh

Jimmy S. Jackson is Vice President of Pharmacy Services and Governmental Affairs for Kerr Drug Stores, Inc., based in Raleigh. He received his BS in Pharmacy from the University of Mississippi in 1967.

Jimmy has been a member of the North Carolina Pharmaceutical Association for 15 years. Presently, he is an advisor to the NCPhA State Legislation Committee and serves on the Pharmacy in the 21st Century Commission. He has served on the following NCPhA committees: Nominations, Third Party, Continuing Education (as Chairman), and as the chairman of the State Legislation Committee. He is the immediate past President of NC PharmPAC. In 1990 he received the Don Blanton Award from the NCPhA. He also serves on the NCPhA Executive Committee.

In addition to his NCPhA activities, Jimmy serves as secretary of Pharmacy Network National Corporation and has served on its Executive Board since it began. He is a member of the NC Retail Merchants' Association and has served as chairman of its Chain Drug Committee since 1988. He has participated in the NC Board of Pharmacy's Leaders' Forum since 1986.

On the national level, he is a member of the NACDS and its State Government Affairs Committee, the Roche Chain Drug Advisory Board and the Burroughs Wellcome Chain Advisory Board.

Jimmy chaired the Redistricting Committee for Garner in 1991, and also served on the Economic Development committee in 1991. He is also an active member of the Rotary Club of Garner. Jimmy was also recently elected to the Board of Directors of the Chamber of Commerce in Garner and serves on the town Economic Development Committee. Jimmy also serves on the Corporate Advisory Board of the N.C. Academy of Family Physicians.

"I see the Association's principal functions as the preservation and furtherance of the profession.

"As Pharmaceutical Care furthers our responsibility to the patient by adding duties toward achieving specific outcomes, the Association must move cautiously into these new uncharted waters.

"One of the processes assigned to the pharmacist in Pharmaceutical Care is the development of a therapeutic plan that will produce specific outcomes. Hospital pharmacists have been involved in this process for years, but involving the retail pharmacist in the planning process will be difficult. Retail pharmacists by using fax machines, remote computer monitors, etc., may be able to overcome some of the obstacles.

"The Association must receive input from the state's pharmacy schools, government leaders, and most importantly, practicing pharmacists to let Pharmaceutical Care evolve carefully.

"At a time when cost control is being demanded by third party payors, government agencies and large employers, care must be taken to assure that we not assign further responsibilities to our profession without finding ways to receive payment for these added services."

★ FOR MEMBER-AT-LARGE ★

(two to be elected)

Randy G. Ball
Wake Forest

Randy Ball is a pharmacist with Revco in the town of Wake Forest. Randy has a diversified professional background, having worked as a pharmacist and consultant with alcohol and substance abuse rehabilitation and more recently has extended his practice into Geriatric Pharmaceutical Care to several nursing and rest homes.

Randy is an active member of NCPhA and currently serves on the Retail Community Pharmacy Committee, Resolutions Committee, and the Membership Development Committee. He has served on the Nominations Committee, Constitution and Bylaws Committee and the Community Pharmacy Committee. In 1990, NCPhA honored Randy as North Carolina Young Pharmacist of the Year. Randy is also a member of the Wake County Pharmacy Association and has served on its executive committee.

"This is an important time for pharmacy in North Carolina. Healthcare has moved from the hospital to ambulatory community-based care and our profession has evolved towards an information based practice. These transitions afford many opportunities for practitioners to provide community based pharmaceutical care. As part of this evolution, NCPhA must become the leading force in the implementation and definition of Pharmaceutical Care in North Carolina. NCPhA needs strong leadership with clear vision as to the future of Pharmaceutical Care to better determine our direction in meeting future demands on pharmacists. We must not allow other interest groups to dictate the practice of pharmacy in this state. NCPhA should establish the standards and encourage development of Pharmaceutical Care by:

1) Being proactive in the legislative arena to promote positive pharmacy legislation.
2) Providing diversified CE at yearly conventions to better address our information needs in our chosen practice settings.
3) Promoting the importance of Pharmaceutical Care to the public.
4) Developing professional recognition.
5) Encouraging fair compensation for pharmacists using their expertise in the care of their patients.

"I would be honored to serve NCPhA and its membership and appreciate your support."

Robert S. Beddingfield
Pinehurst

Robert S. "Bob" Beddingfield is the director of pharmacy at Moore Regional Hospital in Pinehurst.

In addition to being a member of NCPhA for many years, he is also a member of NCSHP and ASHP. He has served on many NCPhA committees, including Continuing Education, Nominations and Resolutions.

He is a member and past president of the

Moore County Pharmacists' Association. Bob is a Life Member and a past president of the UNC Pharmacy Alumni Association.

"NCPhA must play the cohesive part in Pharmaceutical Care. Different associations are working toward this goal but the North Carolina Pharmaceutical Association is the one unit that can be all inclusive for independents, chains, hospitals, education, industry, and research pharmacists.

This association must be literally pharmacists working as associates without regard to practice setting. A few years back when serving on the Nominations Committee, I was alarmed by the apparent divisiveness within the association and the territorial positions with reference toward retail, education or hospital settings. Over the last few years, there seems to be a change toward more unity. Pharmacy's cause will be best served if this trend continues.

Pharmaceutical Care will only take place when it is a continuous effort. Patient outcomes do not stop at the exit door of the retail store or hospital. It must be carried through every area.

It is an honor to be considered for this position. Over the last 20 years I have seen many changes. I look forward to serving our association in any way that is needed."

Charles L. Hill
Charlotte

Charles L. "Roy" Hill is a 1988 graduate of the UNC School of Pharmacy and is a pharmacist for Peak Drugs, Inc. in Charlotte. Roy has been a member of the NCPhA for 7 years and has been active in the Mecklenburg Pharmaceutical Society. He has served on several committees, including his current positions on the Legislative Committee and the Third Party Committee (of which he is past chairman). Roy serves on the PharmPAC Board of Directors and is a 1992 Graduate of the S.K.B./APhA APPLE Pharmacy Management Program. He has also been a facilitator in Patient Consultation Workshops.

"The process of implementing Pharmaceutical Care will be a complex and multi-faceted one. It should be our responsibility as a pharmaceutical association to represent our membership in the professional, political, economic, and academic arenas of Pharmaceutical Care. All this is done keeping in mind that Pharmaceutical Care involves the provision of services as well as goods.

"Pharmaceutical care requires close and detailed interactions with other health care professionals. We should promote and encourage these interprofessional and intraprofessional relationships. Many of the dramatic and fast paced changes in pharmacy are driven legally by political actions (OBRA '90). It should be the responsibility of the staff and elected officials to monitor these moves and alert the membership to actions they may need to take. Much of this political action is economically driven and is bound to change dramatically over the next several years. Where Pharmaceutical Care falls in these changes will depend on the emphatic input of organizations such as our NCPhA. This will be in the private pay, insurance, and government reimbursement circles. NCPhA should also provide guidelines and opportunities for students and membership to learn how to balance the therapeutic and ancillary areas of Pharmaceutical Care."

Retain this important information about your NCPhA candidates so that you can refer to it when your ballot arrives in the mail.

Mary Ann Largen
Charlotte

Mary Ann Largen is the pharmacy director for a 5-store Drug Emporium franchise.

She has been a member of NCPhA for six years. Largen is currently chairman of the NCPhA Professional and Public Relations Committee and past chairman of the Employer/Employee Relations Committee. She served as a delegate to the NARD House of Delegates this past October in Baltimore, MD. She was appointed by the governor to the State Medicaid Drug Utilization Review board to serve until January, 1994.

Largen is the pharmacist member of the Medical Advisory Board to Planned Parenthood of the Southern Piedmont and Carolina Mountains. She is also a member of APhA and NARD.

"Poor Pharmaceutical Care is costly in financial terms as well as health outcomes. It affects all of us as taxpayers, insurance providers and recipients and especially as health care providers. Education is the key to improving self-care and maximizing therapeutic outcomes.

The role of the NCPhA over the coming year should be two-fold:

1) To actively recruit participation of all pharmacists in the association.
2) To offer exceptional educational opportunities to pharmacists in areas of counseling and communication skills.

"The lack of participation in the past has been due to non-members' perception there was little value in membership. However, value would be demonstrated by quality skills training that could be translated into self-confidence in patient-pharmacist interactions. Eventual financial rewards could be realized as a result of superior care. The educational process must begin with efforts of NCPhA to develop programs to attract membership and reward participation."

John A. Mitchener III
Edenton

John A. Mitchener III is a 1963 graduate of the UNC School of Pharmacy. He is past president of the Northeastern Carolina Pharmaceutical Association and a life-member of the NCPhA. He is also a member of the UNC School of Pharmacy Alumni Association and a member of the North Carolina Retail Pharmacy Association.

Mitchener served as a pharmacist with the U.S. Army in Saigon, South Vietnam for 15 months between 1967 and 1969 with the 218th Medical Dispensary and 3rd Field Hospital. Since 1969 he has been a pharmacist with managerial responsibilities at Mitchener's Pharmacy in Edenton.

Three out of the last four years Mitchener has chaired the Social and Economic Relations Committee for the Association. Major proposals from that committee were adopted by the Association last spring at the annual convention in Pinehurst. The result will be improved staffing in Chapel Hill and more effective lobbying in Raleigh.

Mitchener has served his community on the Edenton-Chowan Board of Education for ten years, many as vice-chairman and the past two years as chairman. He was an active proponent of the $7 million Bond Issue successfully passed in 1988 featuring major improvements in middle-school education.

"Pharmacy in North Carolina is a profession at risk: we are told to do more and more while being paid less and less.

"We are threatened by overbearing insurance companies, two-faced Medicaid programs, mail-order companies subsidized by discriminatory pricing, and situations eliminating patients' freedom to choose their pharmacy.

"A major insurance company brags about having 4.02 months of cash-flow reserves now compared to 3.1 months in 1990. Instead of giving patients a break during this recession, this company creates "disadvantages" for all by frustrating prompt and fair reimbursement.

"Beginning in January 1993, Medicaid demands patient counseling, yet never recognizes "time is money" nor speaks of reimbursement for cognitive services. Instead, in December 1992 Medicaid expands a MAC list by 200-plus items highlighted by more decreases in margins than increases.

"In both the private and public sectors, reimbursement based on a flat-fee alone is a recipe for slow death in a time of rising cost of inventory. Revision is essential. Fees plus a percent or percent reimbursement alone is needed.

"The NCPhA is an umbrella organization for all settings of pharmacy in our state–and properly so. But those not in community pharmacy should not regard our troubles with indifference. Permitted to worsen, these troubles will adversely affect other parts of the profession as well.

"North Carolina stripped of one-man pharmacies in its many small towns will hardly be a healthy North Carolina.

"The role, therefore, of the NCPhA in implementing "Pharmaceutica Care" should be an aggressive one of speaking to these issues, proposing constructive alternatives and seeking their implementation through the legislative process. A pro-active membership led by energetic officers can make this happen."

Thomas R. Thutt
Kinston

Thomas R. Thutt is the owner and operator of Medical Center Pharmacy in Kinston.

Thutt has been a member of the NCPhA for 18 years and currently serves as chairman of the Membership Development Committee. He is also on the Nominations Committee and the Tripartite Committee. Tom has served as past chairman of the Continuing Education Committee and Ethics Committee and is a past member of the Third Party and Time and Place Committee. He is a member of the Academy of Pharmacy and serves on the Board of Directors for the Pharmacy Foundation of North Carolina.

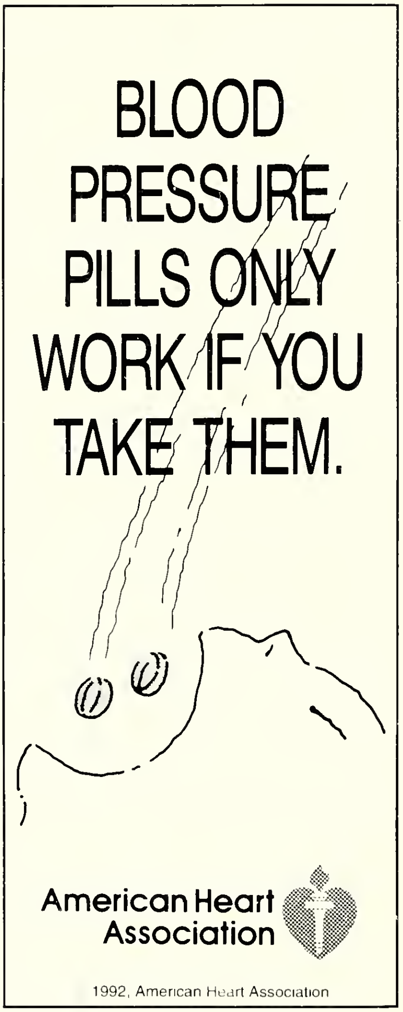
He is secretary of the Down East Pharmacy Society and a member of NARD. Thutt is a UNC Practitioner-Instructor and in 1987 was chosen as the UNC-Syntex Practitioner-Instructor of the Year. In 1991 Thutt was named NARD-Syntex National Preceptor of the Year.

"It is the mission of pharmacy in North Carolina to provide Pharmaceutical Care to the public. That care includes the application of the pharmacists' skills and knowledge as well as the provision of services. The role of NCPhA in implementing Pharmaceutical Care is twofold:

1) to facilitate the educational process by which pharmacists acquire, retain and enhance their skills and knowledge base; and
2) to educate the public of the value and worth of that skill and knowledge.

"The NCPhA will offer continuing education classes which assure that pharmacists provide the best Pharmaceutical Care. An ongoing public service campaign will inform the public of what their pharmacist is doing for them. The NCPhA will then take on all those'other parties' who are trying to destroy pharmacy.

"The NCPhA will be pharmacy's biggest advocate in Raleigh and Durham. It is time to take off the white gloves and start fighting back. Pharmacy is good for health care and it is time we are recognized for that."


BLOOD PRESSURE PILLS ONLY WORK IF YOU TAKE THEM.
American Heart Association
1992, American Heart Association

SMITHKLINE BEECHAM NAMES RECIPIENTS OF THE 1992 PATIENT CARE AWARD

SmithKline Beecham Pharmaceutical has recognized the outstanding work of Michael Dale Hance, a graduating pharmacy student at the University of North Carolina and Lisa M. Harris, a graduating pharmacy student at Campbell University by honoring them as recipients of the SmithKline Beecham Pharmaceuticals 1992 Patient Care Award.

According to George Heil, Manager of Pharmacy Relations for SmithKline Beecham Pharmaceuticals, "Michael, a resident of Lincolnton, and Lisa, a resident of Cary were presented with the SmithKline Beecham Pharmaceuticals 1992 Patient Care Award in recognition of the superior patient care skills that they demonstrated during rotations in both hospital and community practice."

A total of 69 Patient Care Awards are presented by SmithKline Beecham Pharmaceuticals this year to graduating pharmacy students from across the United States.

"Award winners were selected by the college of faculty," says Heil. "Each award winner is presented with a cash award of $250 and an engraved plaque. The winner's name is also added to the names of previous Patient Care award winners from their college of pharmacy on a permanent plaque displayed at their college.

The Patient Care Award was originally established by SmithKline Beecham Pharmaceuticals in 1975 as the Clinical Pharmacy Award and was designed to honor outstanding pharmacy students for their achievements in clinical pharmacy. The award was renamed the Patient Care Award in 1991 in recognition of the emerging patient orientation in pharmacy practice.

DICKINSON'S PHARMACY

DROP BY DROP

Many a pharmaceutical preparation owes its efficacy to the addition of a drop at a time.

So it is with pharmaceutical causes. But in this age of ready-prepared medications, the patience to persist, drop by drop, in a cause is often missing.

I am learning the value of persistence and of a drop at a time in my four-year quest at the Food and Drug Administration to have mail-order "pharmacy" regulated by that agency. (I always put inverted commas around "pharmacy" when it follows the term "mail-order," not to cause offense to those noble and well-educated pharmacists who toil in mail-order prescription factories, but to keep alive my view that what goes on in those facilities is not real-world pharmacy—not that I have ever been inside one, because all my requests for admittance have been sneeringly rejected by their owners. "Do you blame us, with your reputation?" some have replied—to which I say, "You must be terribly scared!")

FDA has agreed to re-examine my 1988 petition, which it rejected in late 1990, on the basis of my drop-by-drop persistence, based on the supreme importance of this cause.

Since the original petition was denied—primarily on the grounds that the states were doing a good job in regulating mail-order prescription mills—I have presented new evidence to the agency, one drop at a time.

One "drop" was University of Montana law professor Gregory Monro's *Journal of Legal Medicine* article last fall that described the present regulatory scheme for interstate mail-order prescriptions (i.e., pick your own state to operate in and ignore all the other states' laws) as "courting a future disaster."

Another "drop" was the mail-order industry's American Managed Care Pharmacy Association response to Monro— it said that to comply with "multiple and overlapping state requirements is burdensome to the point of being economically prohibitive." For an industry so awash with money and surplus profits that it is the perpetual darling of Wall Street, that confession rang alarm bells all over FDA.

Yet another "drop" was FDA's investigation of interstate pharmacy "compounding" operations that it viewed as actually amounting to illicit generic drug manufacturing operations, because of the huge volume involved. Speed and volume, of course, are what make mail-order "pharmacy" so dangerous—no different in that respect than the contested "compounding" operations.

Now I'll admit that FDA is barking up the wrong tree on the compounding issue—most of the pharmacies it sent warning letters to were doing only honest, traditional compounding. By setting limits on the practice of pharmacy just to catch a few illicit "manufacturers" disguised as high-tech pharmacies, FDA is using a sledge hammer to swat a fly (and breaking up the house of pharmacy in the process).

But there may be a silver lining in FDA's clumsy interest. It has seen the dangers of unregulated interstate prescription shipments in a new light.

You might ask: Aren't you counting your chickens before they're hatched? Just taking a second look doesn't mean FDA will regulate interstate mail-order prescriptions.

To which I'd say— but it's another "drop." Drop by drop, we'll get there. If FDA turns us down this time, it will likely do so in a manner that will open new doors, so we can come back again.

And then there's the question many ask—

Do we want the feds in pharmacy at all, even if it's only to regulate mail order? You know, toe in the door, and soon they'll take over other things.

It's a shrinking world. In Europe, the national governments are handing over their powers to the EEC. Some even see a World Government in the future.

I don't like any of this any more than you do and I'm skeptical that it will ever really come about. But we do have to bend a little in the tide of events that trend this way and that.

The tide in pharmacy has been toward mail-order for maintenance drugs. The economics don't make sense, because waste overcomes the paper savings—but to quote an old huckster from the turn of the century, "there's a sucker born every minute." There seems to be an unlimited supply of new health benefits "suckers" out there who will buy the mail-order savings mirage.

The worst thing is that often they fall for the mirage before community pharmacy groups are even aware the plan is hunting for price breaks.

In the high-speed, high-volume world, a modest FDA requirement that interstate mail-order prescription factories maintain complaint files for FDA inspection, and that they directly report to FDA any error that escapes into the mail, is a small price to pay for a necessary element of consumer protection.

If mail-order is as dangerous as we believe it is, publicity about FDA's many discoveries from mandatory complaint files and direct reporting will help bring a "level playing field" to the pharmacy benefits business, which increasingly disadvantages community pharmacy now.

So if you know of a mail-order error, tell FDA about it, referencing Petition No. 91P-0414/CP, Dockets Management Branch, FDA-HFA 305, 12420 Parklawn Drive, Rockville, MD 20857.

One drop at a time, we'll fill FDA's bucket of concern!

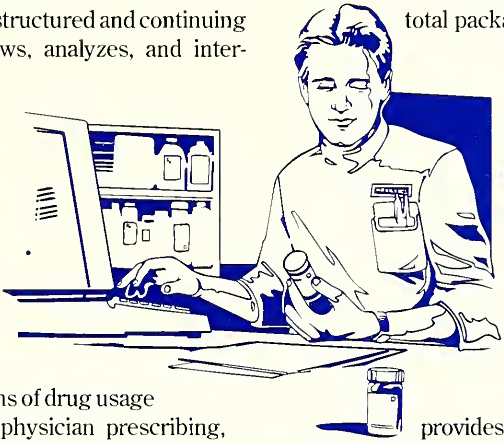
This feature is written and presented by Jim Dickinson on a grant from "Dickinson's Pharmacy–The Independent Voice," a professionally stimulating monthly newsletter, available for $45 a year plus your retail pharmacy's label from Ferdic, Inc., P.O. Box 367, Las Cruces, NM 88004-0367. NCPhA accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of NCPhA.

Linda Swindler presents NCPhA member Bill Oakley of New Bern an award of merit as Allen Hayes stands by. Swindler and Hayes, with Merck Human Health Division, made the award on behalf of Merck & Co. to recognize professional and civic achievements by Oakley.

A PHARMACIST'S GUIDE TO DRUG UTILIZATION REVIEW

The advancement of drug therapy continues to be an important contribution to improved healthcare. Pharmaceutical therapy is generally recognized as one of the most effective and economical methods of preventing, treating, and curing illness and disease. In an effort to ensure that drug therapy is optimal, utilization review programs have been established. One type, Drug Utilization Review (DUR), examines physician prescribing, pharmacist dispensing, and patient use of drugs.

Drug Utilization Review is a broad term and may be defined as a structured and continuing program that reviews, analyzes, and interprets patterns (rates and costs) of drug usage in a given healthcare environment against predetermined criteria and standards.[1] DUR may be quantitative in nature and focused on aggregate patterns of drug usage through review of physician prescribing, pharmacist dispensing, and patient use of drugs. It may also be qualitative in nature and focused on a specific patient with a complex medical regimen.



The Primary Goal of DUR is to Improve the Quality of Patient Care

The primary goal of drug utilization review is to enhance and improve the quality of pharmaceutical care and patient outcomes by encouraging optimal drug use. This goal is accomplished primarily by educating physicians and pharmacists. Ensuring that drug therapy is appropriate, safe, and effective can prevent the occurrence of many adverse medical reactions and other significant consequences. As a result, a combination of drug therapy review and educational intervention activities may contribute to improvements in quality of care and patient outcomes. Effective DUR ensures that the type and duration of drug therapy is appropriate for the condition being treated in individual patients.

There are Three Basic Types of Drug Utilization Review

The three types of drug utilization review are prospective, concurrent, and retrospective. Each type has a role in the total package of pharmaceutical care; none can stand alone. To be truly effective, all three types must be present.

Prospective DUR is performed before the medication is dispensed to the patient. It is a systemic evaluation of medication therapy for a patient. This review provides for an immediate medication screen against predetermined criteria and standards which may include allergy, contraindication, duplicate therapy, and drug interactions. Prospective DUR is essentially a quality assurance process oriented towards enhancing the therapeutic outcomes of pharmacologic agents.

Concurrent DUR is performed while therapy is in process and is generally limited to inpatient institutions or patients on long term therapy. Examples include reviewing or altering antibiotic therapy after receiving the culture and sensitivity test results or monitoring and reviewing the long-term effect of antihypertensive therapy on stroke prevention.

Retrospective DUR is conducted after medication is dispensed. In many cases, the review is conducted long after the medication has been dispensed. Retrospective DUR allows patterns of physician prescribing, pharmacist dispensing, and patient use of medication to be analyzed in support of quality assurance, cost containment, and risk management initiatives.

DUR is Not a New Concept

In 1969, The Task Force on Prescription Drugs, Department of Health, Education and Welfare, described DUR as "a dynamic process aimed first at rational prescribing and the consequent improvement of quality of care, and second at minimizing needless expenditures."[2] Since 1969, regulatory bodies, such as the federal government and the Joint Commission on Accreditation of Healthcare Organization (JCAHO), formerly the Joint Commission on Accreditation of Hospitals, has been involved in the development and expansion of DUR.

The Health Care Financing Administration (HCFA) published regulations in 1974 pertaining to the Medicare and Medicaid programs. These regulations required pharmacists to perform monthly drug-regimen reviews for persons residing in skilled-nursing facilities.

In its *Accreditation Manual For Hospitals* (1978), the Joint Commission on Accreditation of Hospitals required that antibiotic utilization review be conducted in a hospital in order for the hospital to be accredited by the Commission.

The Health Care Financing Administration State Operations Manual for Provider Certification (1982) included guidelines for long-term care certification surveyors to use in assessing drug regimen reviews by providing a list of indicators of potential drug problems which may be encountered in the facilities.

In 1986, the JCAHO *Accreditation Manual for Hospitals* expanded the concept of drug usage evaluation beyond the scope of antibiotics. The objective became a comprehensive review of drug therapy in an effort to improve patient outcomes. JCAHO defines DUR as a "criteria based, on-going, planned and systemic process for monitoring and evaluating the prophylatic, therapeutic, and empiric use of drugs to help assure that they are provided appropriately, safely, and effectively."[3]

The Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203) included provisions to expand drug regimen reviews conducted within skilled-nursing facilities to include intermediate care facilities. In addition, it required pharmacists to perform the reviews for all these patients, eliminating drug regimen reviews previously performed by registered nurses in intermediate care facilities.

Although repealed, the Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) would have provided outpatient prescription drug coverage and for an educational program to inform physicians and pharmacists about quality of care issues.

The Omnibus Budget Reconciliation Act of 1990 Requires State Medicaid Programs to Implement Prospective and Retrospective DUR Programs

Drug utilization review continues to be a mechanism that federal legislators believe is useful in improving the quality of patient care as well as containing government health care expenditures. Most recently, the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) mandates that each state Medicaid program implement a retrospective and prospective DUR program by January 1, 1993.

OBRA-90 stipulates that the state Medicaid DUR programs be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse or inappropriate or medically unnecessary care. The DUR program for covered outpatient drugs must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical reactions.

State Medicaid Programs Have Some Flexibility in Selecting a DUR Board

Each state must establish a DUR Board either directly or through a contract with a private organization. OBRA 90 requires that the DUR Board membership be composed of at least one third but no more than 51 percent licensed and actively practicing physicians and at least one third licensed and actively practicing pharmacists. OBRA-90 gives states the flexibility to determine how many members will serve on the Board. The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

- clinically appropriate prescribing of covered outpatient drugs;
- clinically appropriate dispensing and monitoring of covered outpatient drugs;
- drug use review, evaluation, and intervention; or
- medical quality assurance.

The DUR Board Primarily Develops Recommendations for Establishing DUR Policy

The primary role of the DUR Board is to develop recommendations concerning DUR policy to the state Medicaid Agency. The draft OBRA-90 DUR implementation guidelines issued by HCFA in November 1991 outline the following responsibilities of the DUR Board:

- establishing and/or approving the standards and criteria;
- making recommendations for the development of new and modification of existing criteria and standards;
- making policy recommendations with regard to maintaining confidentiality of patient related data;
- evaluating prospective DUR software and written prospective DUR criteria to determine whether these tools meet statutory requirements;
- making policy recommendations concerning the appropriate mix of education and intervention approaches to be carried out as part of retrospective DUR and evaluation of the results;
- preparing an annual report describing the nature and scope of the DUR program; and
- summarizing education/intervention strategies used and estimating the cost savings.

Constructing Therapeutic Criteria is an Ongoing Process

Developing clinically relevant therapeutic criteria and standards is essential to the effectiveness of drug utilization review. In 1973, the National Professional Standards Review Organization (PSRO) Council defined utilization review criteria as predetermined elements against which aspects of the quality of medical service may be compared. They are developed by professionals relying on professional expertise and on professional literature. "The PSRO Council defined "standards" as "professionally developed expressions of the range of acceptable variation from a norm or criteria."[4]

The state Medicaid DUR program must assess data on drug use against criteria and standards consistent with peer-reviewed medical literature AND the following compendia:

- the *American Hospital Formulary Service Drug Information;*
- the *United States Pharmacopeia-Drug Information;* and
- the *American Medical Association Drug Evaluations.*

The state Medicaid DUR program criteria may be developed by a variety of organizations or entities such as the Medicaid Agency, academicians, commercial vendors of DUR services, or other professional organizations knowledgeable in the development of criteria. The DUR Board must approve the criteria and standards which, according to HCFA's draft implementation guidelines, specify that the criteria must be:

- clinically based and scientifically valid;
- constructed using an open professional consensus process;
- tested and reviewed prior to implementation;
- consistent in application to prospective and retrospective DUR;
- available to the public for comment; and
- readily available to providers upon adoption.

To be effective, the DUR criteria will require ongoing modifications in order to accommodate the dynamic health care environment. In constructing criteria, attention should be given to the increasing number and diversity of available pharmaceutical products, and the progress of new technology in the development of drug products.

State Medicaid Prospective DUR Programs Under OBRA-90

OBRA-90 requires the state Medicaid plan to provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving Medicaid benefits. Within OBRA-90, there are three major components of Medicaid prospective DUR:

- therapeutic screening;
- patient counseling; and
- maintenance of patient records.

Screening for the specific therapeutic problems may be accomplished using explicit written criteria or by using criteria-based computer software. This therapeutic screening includes:

- therapeutic duplication;
- drug-disease contraindications;
- drug-drug interactions;
- incorrect drug dosage or duration of drug treatment;
- drug allergy interactions;
- clinical abuse/misuse.

Under OBRA-90, a part of the state's prospective DUR program must, under applicable state law, establish standards for counseling of Medicaid patients by pharmacists. OBRA-90 sets broad guidelines requiring pharmacists to offer to discuss with the patient or caregiver (in person whenever practical, or through a toll-free telephone service) matters which, in the professional judgement of the pharmacist, the pharmacist deems significant, such as the name and description of the medication, proper storage, common severe side effects, the dosage and duration of drug treatment, and other pertinent information. By enhancing the communication between the pharmacist and the patient, counseling may contribute to improving compliance.

Pharmacists must also make a reasonable effort to obtain, record, and maintain patient information in records or profiles. By maintaining such profiles, the pharmacist can more effectively counsel the patient on his/her drug therapy. These profiles may contain the following information:

- name, address, telephone number;
- age and gender;
- individual medical history where significant including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant medical devices currently in use by the patient; and
- pharmacist's comments relevant to the individual's drug therapy.

State Medicaid Retrospective DUR Programs Under OBRA-90

OBRA-90 requires that the state Medicaid retrospective DUR program provide for the periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and Medicaid recipients.

Monitoring may focus both on patterns of prescribing by physicians and on the use of drugs by the individual patient. Retrospective utilization review may produce exceptional profiles on specific drugs, physician and pharmacy providers, and/or individual patients depending on the scope of the predetermined criteria.

OBRA-90 provides that retrospective DUR must include (but is not limited to) monitoring for:

- therapeutic appropriateness;
- overutilization;
- underutilization;
- appropriate use of generic products;
- therapeutic duplication;
- drug-disease contraindications;
- drug-drug interactions;
- incorrect drug dosage or duration of drug treatment;
- clinical abuse/misuse.

The DUR Board is Responsible for Educational Activities

The DUR Board must provide for active and ongoing programs to educate physicians and pharmacists about common drug therapy problems with the goal of improving prescribing and dispensing practices. The Board may provide these programs directly or through contracts with accredited health care educational institutions, state medical societies, or state pharmacists associations/societies or other organizations.

Educational outreach programs or interventions for physicians and pharmacists may be focused on individuals or on therapy problems. The interventions should include at the minimum:

- dissemination of information sufficient to ensure physicians and pharmacists understand the duties, powers, and basis of the program;
- written, oral, or electronic reminders containing patient-specific or drug-specific information;
- suggested changes in prescribing or dispensing practices;
- use of face-to-face discussions between healthcare professionals who are experts in rational drug therapy and selected physicians and pharmacists; and
- intensified review or monitoring of selected physicians and pharmacists.

The DUR Board should recommend the mix of appropriate educational strategies. Evaluation of interventions should be conducted after an appropriate time to determine if the intervention improved the quality of the drug therapy. In this way, the evaluation is more meaningful in terms of the success of the interventions, and relevant modifications can be made as necessary.

Separations of SUR and DUR within State Medicaid Programs is Required by OBRA-90

Since the early 1970's, state Medicaid programs have been required to have systems for identifying and investigating cases of potential fraud and abuse. Many states rely on the Surveillance Utilization Review (SUR) unit of the Medicaid agency to identify and regulate fraud and abuse.

The SUR unit primarily attempts to identify overuse or misuse of a program and then may recoup costs. Depending on the nature and severity of the case, sanctions, including criminal prosecution and civil monetary penalties, may be imposed.

In contrast, the DUR program under OBRA-90 is designed to examine pharmaceutical care and provide education to physician and pharmacy providers to improve patient care and health-care outcomes.

Since functions performed by the SUR and DUR programs overlap to some degree, the state Medicaid plan should clearly delineate the goals, objectives, and responsibilities of each program as well as how they interrelate. Strict operational separation between the SUR fraud and abuse and the DUR educational/intervention efforts should be maintained.

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Provided courtesy of Searle's Pharmacy Affairs/State Health Services Department through Drug Utilization Review Forum, Vol. 1, No. 1, Summer 1992

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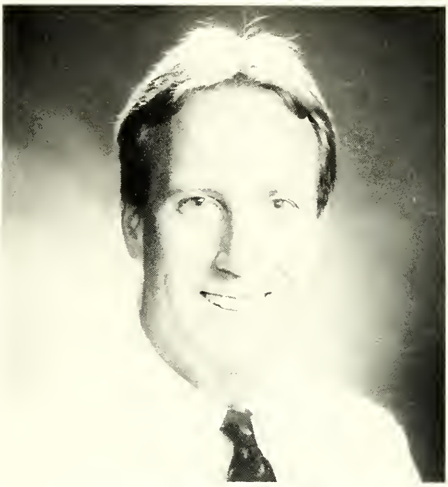
DEA REGULATIONS ON REGISTRANT EMPLOYMENT PRACTICES



Steven M. Fisher, J.D.

Under current Federal law, distributors of Schedule I through Schedule V controlled substances are required to be registered with the U.S. Attorney General unless that registration is inconsistent with the public interest. When registering an applicant, the Attorney General considers factors such as the maintenance of an effective control system against diversion, previous compliance with state and local law, the prior conviction record of the applicant under laws relating to the manufacture, distribution, or dispensing of controlled substances, the past experience of the applicant in distributing controlled substances, and other factors relevant to the public health and safety. The Attorney General has the authority to deny, revoke, or suspend a registration if a registrant materially falsified an application, was convicted of a felony under any applicable United States or state law relating to a controlled substance, or has had a state license for registration suspended, revoked, or denied by an applicable state authority.

The Drug Enforcement Administration of the Justice Department has now extended its regulations to prevent a registrant from employing as an agent or employee another person who has been convicted of a felony offense relating to controlled substances or who has surrendered a registration as a consequence of a controlled substance investigation, if that employee has access to controlled substances in the course of his or her work. Essentially, this regulation prevents a D.E.A. registrant from hiring anyone who would probably be denied a registration of their own if they applied as a practitioner.

This new employment regulation impacts numerous situations, given that a vast majority of nurses and pharmacists are not D.E.A. registrants, but rather agents of D.E.A. registered hospitals, pharmacies, physicians, or other entities. Its language, "felony offense relating to controlled substances," appears not to preclude hiring an individual unless the felony offense involves some actual illegal distribution or receipt of a controlled substance. Therefore, a conviction for overbilling Medicaid, or some other offense not actually involving the diversion of drugs, probably does not preclude employment; however, this employment regulation is new, and this interpretation has not yet been adopted. If a registrant wishes to employ someone who has been convicted of a felony relating to controlled substances, the registrant should attempt to obtain a waiver from the D.E.A. This is possible if the registrant can show they have been fully informed about the potential employee's past experience, and can demonstrate that the registrant intends to take adequate measures to insure against any increased risk of diversion by the employee.

Finally, the D.E.A. requires screening procedures when employing non-practitioners. This screening program should include questions concerning whether the potential employee has been convicted of any felony within the past five years, or any misdemeanor within the past two years, or whether the employee is presently formally charged with a criminal offense. This excludes traffic violations and juvenile offenses. An employer should also inquire as to whether a potential employee has in the past three years knowingly used any narcotics, amphetamines, or barbiturates, other than those prescribed by a physician. These questions, along with the application to the D.E.A. for a waiver in an appropriate situation, will help protect a registrant from violating current Federal regulations in employment practices.

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THE ONE SYMBOL FOR PHARMACY

INCREASED COMPLIANCE: MAKING PATIENT COUNSELING WORK

Edward J. Hesterlee, R.Ph.
Director, Pharmacy Relations
Marion Merrell Dow, Inc., Kansas City, MO

Nearly 50 percent of the population deviate from their medical regimens. As a result, they are not taking advantage of their medications' ability to improve life and well being. What's more, noncompliance can lead to additional unnecessary health care expenses, as well as serious—sometimes life-threatening—consequences.

You, as the pharmacist, are the last member of the health care team to have direct contact with your patients before they administer their own medication. Not only is it important that your patients trust your expertise, it is your responsibility to provide them with as much information about their medical regimen as possible.

What Constitutes Noncompliance?

Noncompliance is more than forgetting to take medications. Noncompliance encompasses a variety of behaviors that need to be identified before being addressed.

Patients suffering from an asymptomatic condition might feel better before their prescription runs out, sometimes causing them to wrongly assume they are "healed." Feeling better, they may prematurely discontinue their prescription, not refill their prescription as directed, or may be late in getting the prescription refilled.

Many times, noncompliance will go from one extremity to another. Patients omit doses of medication, ignore labeling, take outdated medication, or take medication prescribed for someone else. All of these constitute noncompliance and need to be addressed to the best of your ability.

Communication

Noncompliance is not inevitable. Open communication between you and your patients is the key to increasing compliance. Without that vital communication link, your patients may leave your pharmacy without understanding the prescription.

Communicating effectively with your patients and explaining their prescription needs requires the following:

- Clear and simple instructions—Don't be too clinical in your explanations; use terminology your patients understand. Be focused, specific, and brief.
- Active listening—Listen carefully to what your patients are saying and respond accordingly. Don't trivialize their concerns, because

their concerns could indicate possible reasons for noncompliance.

- Ability to "read" your patients—Your ability to "read" your patients by observing their behavior and analyzing body language will help you determine how much and what kind of information to provide. If patients look as if they are losing interest or becoming distracted, redirect the conversation, give them your phone number, provide written materials, and ask them to contact you with questions and concerns.
- Direct feedback—Not only do you need to educate your patients, your patients need to educate you. Patients disclosure of problems is vital in understanding and ensuring the effectiveness of their medical regimens.

Understanding the process and practicing these steps in good faith can help increase compliance in your patients.

Education

Don't assume that your patients will understand how to take their medicine after reading the label. Patients need to be educated about their medical regimens. Here are a few simple steps to make this effective:

- Show the medication with any accompanying product literature to the patient.
- Tell them the name of the drug and its purpose as it related to their condition.
- Explain the medication's dosage, specifically how often and when to take the medication.
- Specify drug interactions, i.e., food, drinks, other drugs, and activities to avoid while administering the prescription.
- Describe common side effects and what to do if they experience any of these.
- Emphasize to your patients that they can call you with questions or concerns about their medications.
- Provide written information to reinforce and supplement your oral communication.

Verification

The information you share with your patients will make a difference only if they understand it. To do this, include a verification step in all of your counseling sessions. Ask your patients to repeat your instructions, using open-ended questions so they have to answer with more than just a simple "yes" or "no." Encourage your patients to ask you questions. Patient counseling should be a dialogue, not a monologue. If you monopolize the counseling session, chances are good that your patients may not ask questions because they feel intimidated. Empower your patients so they can play an active role in the consultation.

Another effective way to verify their understanding is to have them demonstrate—if devices are necessary—the proper technique involved in administering the medication. Remember, people learn visually and by repetition. As a reinforcement step, involve family members in support of supervisory roles whenever needed.

When emphasizing compliance to your patients, keep all of the above factors in mind. Involve your patients in counseling by making it a team effort. Encourage an "ownership" approach with your patients. With practice and commitment, your counseling efforts will be successful.

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Remarks by
David A. Kessler, M.D.
Commissioner of Food and Drug Administration
Pharmacy Conference
National Association of Chain Drug Stores

I'm here today to give the perspective of the FDA on three important public health issues: counseling patients about the medications they take, direct-to-consumer advertising of prescription drugs, and pharmacy compounding.

These are important topics—for the pharmacy profession and for the FDA as well. Since I only have a few minutes, let me get right to the point.

Patient Counseling

When it comes to **patient counseling**, the question for pharmacists is no longer "Should I counsel?" but "What should I say?"

It's clear from the title of this session—and from the video we just saw—that reimbursement procedures will greatly influence the practice of pharmacy. It's equally clear that patients expect their pharmacies to do more than simply provide medications.

In my view, the long-term survival of pharmacy as a profession will depend on the delivery of services—the most important of which will be the pharmacist's role in counseling patients about the drugs they take.

If we are to achieve safer and more effective drug use in this country, we must do a better job of communicating with patients. We must bridge the gap that separates patients from their health care providers.

There are no short cuts. There are no secrets. The best way to communicate to patients about their medications is to combine personal counseling with written information.

Many professions and groups have a stake in this process. Nurses, physicians, consumer groups, and the FDA must all increase their efforts. But pharmacists are ideally suited—because of their training, and their unique position in our health care system— to take the lead. I'll have more to say about that in a moment.

What is the FDA doing to encourage counseling?

In the first place, we are working hand-in-glove with the National Council for Patient Information and Education. The NACDS serves as a member of this group—and Ron Ziegler [President and CEO of NACDS] sits on its board of directors.

You can be proud that Mr. Ziegler worked closely with the White House, getting First Lady Barbara Bush involved in a public service announcement on patient information.

Second, FDA is giving serious thought to improving the "Information for Patients" section that is already included in approved drug labeling for new drugs. Providing a more consistent information base will give health professionals a better idea of the important messages for their patients—and these messages will be available as soon as the drug is approved for marketing.

FDA plays a third role—analyzing the effectiveness of patient information efforts and assessing our progress.

In 1984, FDA found that physicians served as the primary source of prescription drug information. They were about twice as active as pharmacists.

Most often, physicians were found to deliver directions for using the medication appropriately—and less likely to provide cautionary information.

But overall, about one-third of patients failed to receive any meaningful counseling from either their physician or their pharmacist.

Over the next few months, FDA will be repeating this survey, to find out how those numbers have changed.

As a physician, I believe very strongly that all health care professionals should become more assertive in providing meaningful information to patients—both oral counseling and written information.

Pharmacists are uniquely situated to provide both.

And when I speak of written information, I am not thinking about turning pharmacies into reference libraries. I'm thinking, rather, about compact personal computers with sophisticated software. I see computers helping to generate not only general information about a drug, but also targeting information to individual patients.

In this day and age, with inexpensive personal computers and laser printers, it is inconceivable to me that a patient should leave the pharmacy without written advice about how to get the maximum benefit out of their medication.

Let me shift gears and say a few words about another way to communicate to patients: direct-to-consumer advertising.

Direct-To-Consumer Advertising

There's a world of difference between a pharmacist counseling a patient about a drug, and a pharmaceutical firm "pitching" a product. One is patient education, and the other is promotion.

It would be useful if people with a stake in this issue would shift their attention_shift their focus from what happens **before** a drug is prescribed and pay more attention to what happens **after.** Instead of promotional efforts _efforts aimed primarily at increasing the number of prescriptions written_ it would be useful for companies to work with pharmacists to help patients derive the greatest benefit from their medications.

In fact, we are seeing more innovative ways to inform patients about their drugs. Upjohn's new packaging for Halcion provides one innovative approach.

My guess is that such efforts, including unit-of-use packaging and information leaflets, will grow. Patient counseling and information is here to stay. It's in everyone's interest.

Let me conclude by touching briefly on the issue of pharmacy compounding.

Pharmacy Compounding

This is an area where FDA policy is clear, but where we haven't always succeeded in communicating clearly about it.

Here's our position. The FDA has no intention of interfering with the extemporaneous compounding and manipulating of reasonable quantities of drugs, by licensed pharmacists, based on valid prescriptions written for individual patients by licensed practitioners.

Despite the "legalese," our position should be clear. We recognize traditional compounding, as performed by community pharmacists, as an appropriate and valuable professional activity.

Our recent concerns about compounding focus on those who manufacture commercial amounts of drugs **under the guise** of compounding.

Whenever necessary, we will act against those few operators whose so-called "compounding" amounts to large-scale manufacturing and sale of what are unapproved new drugs of unknown safety and efficacy.

Some of these operations even have their own detail persons, marketing consultants, and promotion departments. They buy unapproved drug substances in bulk quantities.

In short, they operate like manufacturers or wholesalers, but without the stringent safety and quality controls of legitimate pharmaceutical companies.

I am confident that the pharmacy profession shares our concern about those few who would **manufacture** drugs_while claiming that they are merely "compounding."

You have my pledge that the FDA will continue to work with state and local officials, the National Association of Boards of Pharmacy, and the Joint Commission of Pharmacy Practitioners to resolve any issues involving compounding.

As a matter of policy, we will generally defer to state and local officials on matters involving the day-to-day practice of retail pharmacy. Mr. Ronald Cheesemore, the man responsible for field operations, will ensure that field offices and headquarters compliance officials work together appropriately on enforcement matters that involve compounding.

I look forward to exploring these issues with you further during the question and answer period.

USP DRUG PRODUCT QUALITY Review
A PUBLICATION OF THE USP DRUG PRODUCT PROBLEM REPORTING PROGRAM

No. 30

PROTECT YOURSELF

A pharmacist from Kentucky submitted a report to the USP Drug Product Problem Reporting (DPPR) Program regarding an oral expectorant liquid, available by prescription. The reporter noticed "a precipitate around the neck of the bottle." He was concerned because there was "no safety seal of any kind" on the product and he wasn't sure if tampering had occurred.

A New Jersey pharmacist submitted a report concerning an over-the-counter (OTC) ophthalmic ointment. A patient had returned the ointment because, when the outer box was opened, the tube was missing its safety seal. The outer box had a statement indicating that a safety seal would be present.

A pharmacist from Texas telephoned USP about a product labeled to contain 175 Acetaminophen Tablets 500 mg. A patient returned the product because it contained 89 Acetaminophen Tablets 500 mg and 84 Acetaminophen Tablets 325 mg. The patient stated that a foil seal covering the bottle opening had been intact when the product was purchased.

An intact safety seal or tamper-resistant packaging indicates to the consumer that a product has not been entered or used. The requirements for tamper-resistant packaging vary depending on the intended route of administration for the product, and on whether the product is available over-the-counter or by prescription only.

USP REVIEW

Tamper-resistant packaging is addressed on page 8 of the *General Notices and Requirements* in *USP XXII* by indicating that all OTC drugs must comply with the tamper-resistant packaging and labeling requirements of the Food and Drug Administration (FDA), unless specifically exempted. Additionally, the container or individual carton of a sterile article intended for ophthalmic or otic use must be sealed so the contents cannot be used without obvious destruction of the seal. This applies to both OTC and legend products, but does not include articles that are extemporaneously compounded for immediate dispensing on prescription. Therefore, with the exception of official otic and ophthalmic products, manufacturers are usually not required to package legend drugs in tamper-resistant packaging since they are not sold directly to consumers. However, OTC products that are sold directly to consumers are subject to the more stringent regulations.

FDA regulations, found in 21 CFR 211.132, provide tamper-resistant packaging requirements for OTC human drug products. An OTC drug product for retail sale (except for a dermatological, dentifrice, insulin, or throat lozenge product) that is not packaged in a tamper-resistant package may be considered adulterated under section 501 of the Federal Food, Drug, and Cosmetic Act. However, a manufacturer may choose to package its exempt products in tamper-resistant packaging.

The regulations state, "to reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with, the package is required to be distinctive by design (e.g., an aerosol product container) or by the use of one or more indicators or barriers to entry that employ an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture) .... A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution and retail display."

The regulations also require that two-piece, hard gelatin capsules are required to have a minimum of **two** tamper-resistant packaging features, unless the capsules are sealed by a tamper-resistant technology. All other OTC products are required to have at least one tamper-resistant feature. All OTC products required to have tamper-resistant features must bear a labeling statement that is prominently placed so that consumers are alerted to the specific features of the package. The labeling statement must be placed so that it will not be affected if the tamper-resistant feature is violated or missing.

General common sense suggestions for consumers purchasing OTC drug products include the following: consider if tamper-resistant features will cause problems in opening the container; look carefully at products for evidence of tampering prior to purchasing; do not purchase products if the protective packaging described on its label is missing or violated; and communicate to the pharmacist any noticeable signs of tampering. If genuine problems do exist, the pharmacist should call the USP DPPR Program.

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CORRESPONDENCE COURSE

NEW DRUGS OF 1992, PART IV: CHEMOTHERAPEUTIC AND ANTIHYPERCALCEMIC AGENTS

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Goals

The goals of this lesson are to identify and discuss new chemotherapeutic and antihypercalcemic agents.

Objectives

At the conclusion of this lesson, the participant should be able to:

1. exhibit knowledge of the pharmacologic and therapeutic classifications for each of the drugs discussed;
2. select indications and mechanisms of action;
3. identify adverse effects, major toxicities, and drug interactions; and,
4. choose important information to use when counseling patients.

Chemotherapeutic Agents

Fludarabine (Fludara/Berlex). Fludarabine is an analog of vidarabine (ara-A; Vira-A), and also related to cytarabine (ara-C; Cytosar-U). It is indicated for treatment of B-cell chronic lymphocytic leukemia in patients who have not responded to other treatments, or in those whose disease has progressed during therapy with at least one standard alkylating agent-containing regimen (e.g., Leukeran).

B-cell chronic lymphocytic leukemia is the most common form of leukemia in the Western hemisphere. It occurs mostly in patients over 50, and affects about 50,000 Americans, with another 9,600 new cases diagnosed annually. It progresses slowly, but is invariably lethal.

Standard therapy for B-cell chronic lymphocytic leukemia has included chlorambucil (Leukeran) plus prednisone. With a response rate of 60 to 80 percent, fewer than 10 percent of treated patients experience complete remission. Fludarabine, in combination with prednisone in one study, effected a response rate of 79 percent in previously untreated patients, with a 33 percent complete response.

While its mechanism of action is not completely understood, fludarabine interferes with DNA synthesis. Following administration, the drug is rapidly dephosphorylated in the liver. After entering the body's cells, it is re-phosphorylated to its active triphosphate, 2-fluoroara-ATP. This is the metabolite that inhibits DNA synthesis.

Adverse effects common with fludarabine include nausea and vomiting, bone marrow depression leading to neutropenia (decreased neutrophils), thrombocytopenia (decreased platelets), and anemia; fever and chills; and increased potential for infection, especially pneumonia. In two clinical trials involving 133 patients, 29 died during the study period. About 50 percent of deaths were due to infection, and 25 percent were from disease progression. A boxed warning appearing in the product labeling includes severe bone marrow depression and severe neurologic effects including blindness, coma, and death. Periodic blood counts should be performed.

Fludara is available as a 50 mg lyophilized powder to be reconstituted with 2 mL of sterile water. This solution if further diluted in 100 to 125 mL of D5W or NSS is used for intravenous infusion. The infusion should be administered within 8 hours of reconstitution.

Fludara is given in daily doses of 25 mg/M^2 intravenously over 30 minutes for 5 consecutive days, with a 23-day drug-free period between each course of therapy. The total number of cycles of therapy has not been clearly established. After the physician believes that an optimal response has been obtained, three additional cycles should be given before the drug is discontinued. Some patients have received up to 15 cycles of the drug.

Pentostatin (Nipent/Parke-Davis). Approved for treatment of hairy cell leukemia in patients refractory to alpha-interferon (i.e., alfa [alpha]-2a/Roferon-A; alfa [alpha]-2b/Intron A), this new drug, isolated from cultures of *Streptomyces antibioticus,* blocks DNA synthesis. Inhibition occurs because pentostatin inhibits adenosine deaminase, which leads to increased levels of deoxyadenosine. This, in turn, inhibits ribonucleotide reductase. Since ribonucleotide reductase is required for DNA synthesis, cell reproduction is inhibited.

Hairy cell leukemia annually affects approximately 2,000 patients in the U.S., with 500 to 600 new patients diagnosed each year. In clinical trials, pentostatin produced 58 percent complete response rates in alpha-interferon-refractory hairy cell leukemia patients, and 28 percent partial response rate. In contrast, data for alpha-interferons at the time of clinical trials included 5 to 10 percent complete response with 60 to 70 percent partial response rate.

During clinical trials, there were several renal, liver, pulmonary and CNS toxicities when pentostatin was used in higher than recommended doses. When used in combination with fludarabine, several patients died as a result of pulmonary toxicity. This information is reflected in the box warning in the product labeling.

At the time of writing of this lesson, studies are in progress to evaluate pentostatin in treating other forms of leukemia. It may also have activity in combating organ transplant rejection.

Nipent is marketed in 10 mg vials for intravenous administration. The patient should first be hydrated with 500 to 1000 mL of 5% dextrose in one-half normal saline solution. Commercially available vials should be stored in the refrigerator. Nipent is prepared by dissolving the lyophilized powder in 5 mL of sterile water providing a solution of 2 mg/mL. This should be administered within 8 hours of reconstitution. Doses of 4 mg/M^2 over 20 to 30 minutes every other week are recommended. Each dose should be followed with 500 mL of D5W.

Teniposide (Vumon/Bristol-Myers Squibb). Teniposide, obtained from the root of *Podophyllum peltatum,* is a semisynthetic derivative of podophyllotoxin. It is similar to etoposide (VePesid) in mechanism of action, efficacy, and toxicity. Teniposide was approved for treatment of refractory childhood acute lymphoblastic leukemia, in combination with other chemotherapeutic agents. It also has a broad spectrum of antitumor activity against hematologic malignancies and solid tumors, including brain tumors, but is not approved for these indications at this time.

Teniposide is cytotoxic through interaction with DNA. It arrests cell division at the metaphase level. It also impairs mitochromal electron transport in the respiratory chain.

Bone marrow depression presenting as leukopenia (decreased leukocytes), pancytopenia (deficiency of all blood cells; aplastic anemia), and thrombocytopenia is the dose-limiting factor. Other adverse effects include nausea and vomiting, diarrhea, and phlebitis at the site of injection.

Physicians are warned to be especially aware of the possibility of hypersensitivity reactions which may occur with the first dose, and be life-threatening if not treated properly. Hypersensitivity manifests as chills, fever, tachycardia, bronchospasm, dyspnea, hypo- or hypertension, urticaria, and facial flushing.

Vumon is not marketed at the time of writing this lesson, but the manufacturer has announced that it will be available in 50 mg (5 mL) ampules. Its dosage is highly individualized. Vumon is to be administered over 30 to 60 minutes by intravenous infusion. The patient should be closely monitored during the infusion and at 30-minute intervals afterwards to watch for hypersensitivity reactions.

Aldesleukin (Proleukin/Chiron-Cetus). Like the interferons, aldesleukin is a lymphokine. Lymphokines are members of a larger group called the cytokines, and are derived from lymphocytes. The term cytokine denotes the soluble protein molecules released within the immune system to communicate an immune or inflammatory response to an antigen. Aldesleukin was originally named T-cell growth factor because it stimulates growth of T-lymphocytes. It is also classed pharmacologically as a biologic response modifier; it promotes immune reactions with malignant cells. Aldesleukin is, therefore, not classed as a chemotherapeutic agent in the traditional sense.

Aldesleukin is another product of recombinant DNA (rDNA) technology. It is also the first drug approved for treatment of metastatic renal cell carcinoma in patients who are asymptomatic and ambulatory. This cancer is relatively resistant to current chemotherapy regimens and kills about 10,000 people a year.

In a series of seven clinical trials, aldesleukin reduced tumor size in 15 percent of 255 patients; 4 percent of patients experienced complete reversal of tumors for 23 months. Eleven percent had a substantial reduction in tumor size for nearly 19 months. Response rate ranges from 6 to 20 percent in most studies.

The exact mechanism of action is not known,

TABLE 1
Currently Available Drugs with Antihypercalcemic Activities

Drug	Strength	Route of Administration	Manufacturer
Calcitonin-Salmon			
Calcimar	200 IU	subcutaneous	Rhone-Poulenc Rorer
Miacalcin	100 IU & 200 IU	subcutaneous	Sandoz
Calcitonin-Human	0.5 mg		
Cibacalcin	vial	subcutaneous	Ciba-Geigy
Etidronate disodium			
Didronel	300 mg/6mL	intravenous	MGI Pharma.
Didronel	200 & 400 mg tablets	oral	Proctor & Gamble
Pamidronate disodium			
Aredia	30 mg/vial	intravenous	Ciba-Geigy
Gallium nitrate			
Ganite	25 mg/mL	intravenous	Fujisawa
Plicamycin			
Mithracin	2500 mcg vial	intravenous	Miles

but aldesleukin stimulates T-cell proliferation and antibody-dependent lymphocyte cytotoxic activity. This results in stimulation of lymphokine activated killer cells as well as natural killer cells. These, in turn, lyse and destroy tumor cells.

The major disadvantage of aldesleukin is its adverse effects which can be life-threatening. In the clinical trials described above, 4 percent of patients died as a result of toxicity to aldesleukin. One life-threatening effect was the capillary-leak syndrome, i.e., the loss of plasma proteins and fluid from the vascular system. Other serious adverse effects include severe nausea and vomiting, angina, hypotension, arrhythmias with myocardial infarction, anemia, respiratory and renal failure, neurologic toxicity, disorientation, and coma. Fever, chills, and malaise often appear within a few hours of administration and can be managed with acetaminophen or a nonsteroidal anti-inflammatory agent. Most adverse effects are reversed within 2 to 3 days of stopping treatment. Continued treatment with aldesleukin does not improve tolerance for adverse effects. Because of its potential for toxicity, aldesleukin is approved for use only in patients with normal cardiovascular and pulmonary functions. There is a strong boxed warning to this effect in the product labeling.

Proleukin will be marketed in single-use vials containing 22 x 10^6 IU aldesleukin to be reconstituted with 1.2 mL of sterile water. This results in a solution containing 18 million units per mL. Its recommended dosage in 600,000 IU/kg diluted in 50 mL D5W to be infused over 15 minutes.

Up to 14 doses may be administered over five days. Following a drug-free interval of nine days, the regimen is repeated. Patient response must be evaluated in four and seven weeks after the course of therapy before retreatment. The extent of antitumor effect and toxic response are directly dependent upon the amount administered. Some patients respond to additional courses of therapy.

Antihypercalcemics

Two new drugs, gallium nitrate and pamidronate, offer moderate therapeutic advantage over previously available therapy for hypercalcemia associated with malignancy. Hypercalcemia is a potentially life-threatening complication of malignancy, and the most common metabolic complication of cancer. It occurs in 10 to 20 percent of all cancer patients, and in up to 40 percent of women with breast cancer.

Mild or asymptomatic hypercalcemia often responds to intravenous saline hydration with or without diuresis. Urine output of approximately 2 L/day is adequate. When conservative measures fail, more specific antihypercalcemic drugs are used. These include those listed in Table 1.

Gallium Nitrate (Ganite/Fujisawa). This is indicated for the treatment of clearly symptomatic cancer-related hypercalcemia that has not responded to adequate hydration. Gallium nitrate inhibits calcium resorption from bone; its precise mechanism of action is unknown.

In one study, elevated serum calcium was reduced to normal in 75 percent of patients with gallium nitrate, compared to 27 percent response in persons who received calcitonin. Normal levels were maintained for a median duration of 7.5 days with gallium nitrate and one day with calcitonin.

Its package insert contains a boxed warning which cautions that concurrent use of gallium nitrate with other potentially nephrotoxic drugs (e.g., aminoglycosides, amphotericin B) may increase the risk for renal insufficiency in patients with cancer-related hypercalcemia. Gallium nitrate is contraindicated in patients with severe renal impairment. Hypercalcemia of malignancy is often associated with impaired renal function *per se*. The package insert states that serum creatinine and urine output must be monitored during gallium nitrate therapy. Other precautions include the recommendation for daily serum calcium testing and twice-weekly phosphorus determinations to check for hypocalcemia and hypophosphatemia.

Ganite is available in 25 mg/mL 20 mL vials. The usual dose is 200 mg/M^2 infused intravenously over 24 hours, for five consecutive days. If serum calcium levels fall to within the normal level in less than five days, treatment may be discontinued.

Pamidronate (Aredia/Ciba-Geigy). This biphosphonate is also known as aminohydroxypropylidene diphosphonate (APD), and is related to etidronate disodium (Didronel). Pamidronate is indicated for treatment of moderate to severe hypercalcemia associated with malignancy, with or without bone metastases. As with other antihypercalcemic drugs, adequate hydration must also be maintained.

Pamidronate's action is to inhibit bone resorption. Although its precise mechanism of action is unknown, it may absorb onto hydroxyapatite crystals (calcium phosphate) in bone, thus preventing the destructive action of osteoclasts. These are the cells that dissolve bone matrix. The number of osteoclasts in bone tissue is reduced after pamidronate therapy.

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Action is demonstrable within 24 hours after initiation of therapy, with normocalcemia reported to remain for seven days after administration of a single intravenous infusion. In a comparative study, patients received a single 24-hour intravenous infusion of pamidronate, or a 2-hour infusion of etidronate daily for three hours. Seventy percent of patients receiving pamidronate compared to 41 percent of patients on edidronate were normocalcemic by day seven.

Pamidronate differs from etidronate in three important ways. First, most studies confirm that pamidronate is approximately 100 times more potent; thus, lower doses of pamidronate may be effective. Second, unlike etidronate which can inhibit growth of hydroxyapatite crystals and thereby reduce bone formation, pamidronate prevents bone resorption at doses devoid of these other actions. And third, pamidronate has a quicker onset and longer duration of action than etidronate.

Adverse effects reported at the 10 percent or higher level include transient fever, electrolyte disturbance, skin irritation at the site of injection, anorexia, nausea, vomiting, and constipation. Since leukopenia occurred in a few patients, those with pre-existing blood dyscrasias must be monitored carefully for the first two weeks following treatment.

Aredia is available in vials containing 30 mg of lyophilized powder. After reconstitution with sterile water, it is administered in doses of 60 to 90 mg of lyophilized powder. After reconstitution with sterile water, it is administered in doses of 60 to 90 mg to treat moderate hypercalcemia (serum calcium 12-13.5 mg/dL), and 90 mg to treat severe hypercalcemia (serum calcium >13.5 mg/dL). Injections are given as single-dose intravenous infusions over a 24-hour period.

Patient Advice About the New Drugs

Counseling cancer patients should be individualized for each drug and for each patient. With the implementation of OBRA '90 counseling and prospective drug utilization review requirements, it is advisable to be aware of the boxed warnings in the product labeling of these drugs. Highlights of boxed warnings are included in the text of this lesson.

CORRESPONDENCE COURSE QUIZ

New Drugs of 1992, Part IV
Chemotherapeutic and Antihypercalcemic Agents

1. Which of the following drugs is indicated for treating refractory childhood acute lymphoblastic leukemia?
   a. Fludara
   b. Nipent
   c. Proleukin
   d. Vumon

2. The labeling of which of the following drugs has a boxed warning about its potential for causing nephrotoxicity?
   a. Aredia
   b. Fludara
   c. Ganite
   d. Proleukin

3. Which of the following drugs is a product of rDNA technology that was originally named T-cell growth factor?
   a. Fludara
   b. Nipent
   c. Proleukin
   d. Vumon

4. Which of the following drugs has a boxed warning against its use in combination with fludarabine?
   a. Aredia
   b. Ganite
   c. Nipent
   d. Proleukin

5. A prescription for teniposide should be filled by dispensing:
   a. Fludara.
   b. Nipent.
   c. Proleukin.
   d. Vumon.

6. Which of the following drugs is indicated for treating B-cell chronic lymphocytic leukemia?
   a. Fludara
   b. Nipent
   c. Proleukin
   d. Vumon

7. The drug that has a boxed warning about its potential for causing blindness, coma, and death is:
   a. Aredia.
   b. Fludara.
   c. Nipent.
   d. Proleukin.

8. Which of the following drugs is indicated for treating patients refractory to alpha-interferon?
   a. Fludara
   b. Nipent
   c. Proleukin
   d. Vumon

9. Which of the following drugs has a warning about its association with the capillary leak syndrome?
   a. Aredia
   b. Fludara
   c. Nipent
   d. Proleukin

10. Pamidronate reportedly inhibits bone resorption by preventing the destructive action of:
   a. osteoblasts.
   b. osteoclasts.

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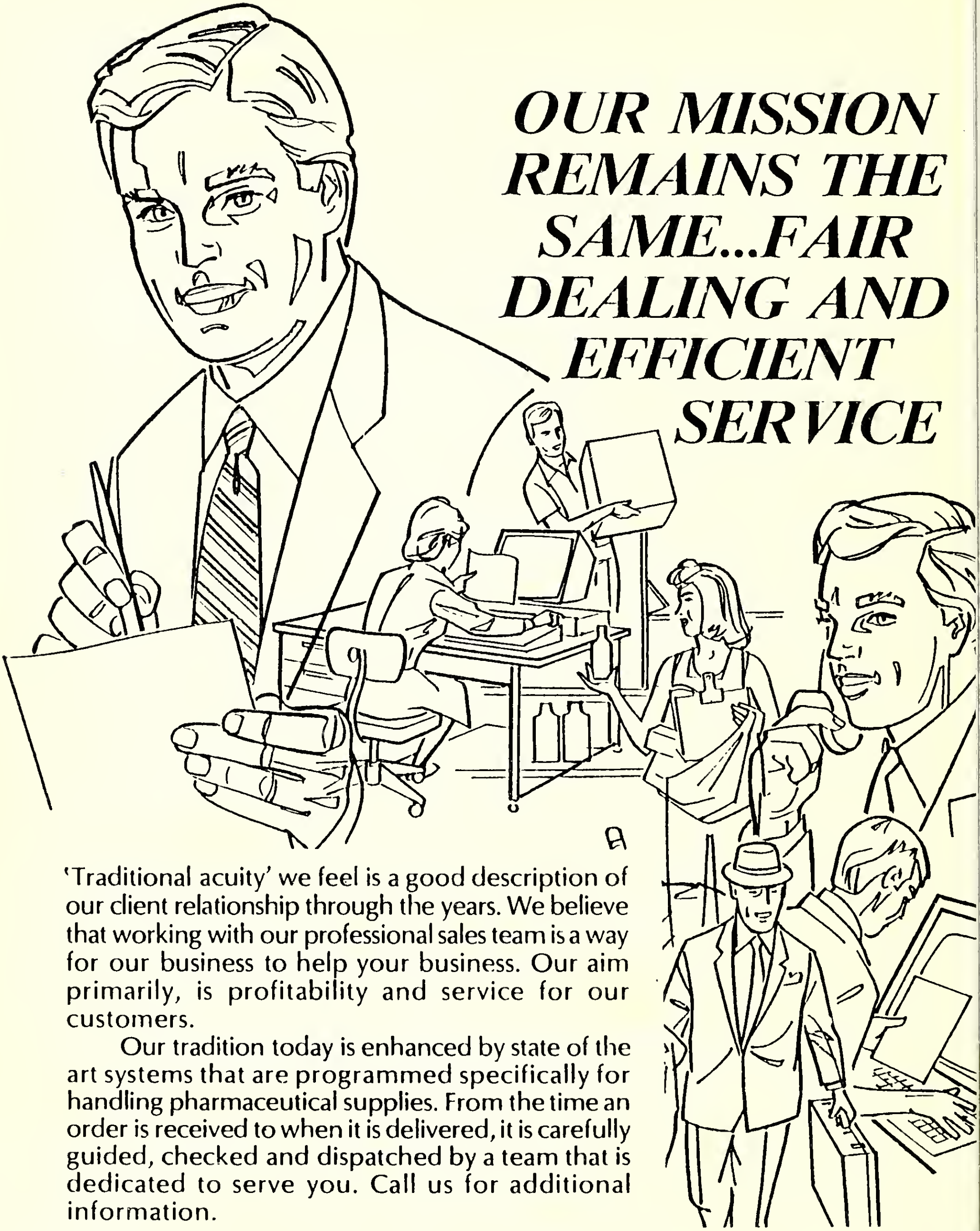
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